



**A DECADE AFTER**  
**HATHI**  
**COMMITTEE**

EDITED BY  
DR. B. EKBAL

KERALA SASTRA SAHITYA PARISHAD

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# **COMMITTEE**

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DR. B. EKBAL



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PARISHAD**

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**A DECADE AFTER  
HATHI COMMITTEE**

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## PREFACE

The Hathi Committee appointed by the Government of India, to study and suggest measures to improve the drug industry in India, submitted its report more than a decade ago. Hathi Committee Report is still considered, both within and outside India, as the most authentic and exhaustive study of the Indian Pharmaceutical Industry. The Committee made it clear that India has developed technological capability for achieving self-reliance in drug production. Hathi Committee recommended that the public sector should be given a leadership role in drug production and that the foreign sector should be taken over by the Government. The Committee published the list of the most essential drugs necessary for the management of the diseases prevalent in India and suggested measures to increase their production so as to reach the needy at low cost.

Unfortunately the recommendations of the Hathi Committee were largely ignored in India, whereas many developing countries have already formulated their National Drug Policies in line with the Hathi recommendations. Even the New Drug Policy announced by the Government of India in 1986 gave away more concessions to the foreign sector much against the spirit of the Hathi recommendations.

Even though the Hathi Committee Report was published in 1975 copies of the report are not available now. Kerala Sastra Sahitya Parishad therefore decided to publish a summary of this report for the benefit of all those who are striving for a People's Drug Policy for our country.

This book contains apart from the Hathi Committee Report, the recommendations of the Pai Committee appointed by the Kerala Government on procurement and supply of drugs and the papers presented at the seminar on Indian Drug Industry organised by KSSP, on 24-25 November 1985 at Trivandrum. This seminar was sponsored by the Indian Council of Social Science Research and the Department of Science and Technology.

We are extremely happy to publish this book on May 24th 1988 the third death anniversary of Dr. Olle Hansson, the Swedish Paediatric Neurologist who fought against the unethical Marketing Practices of Multinational Drug Companies.

Kerala Sastra Sahitya Parishad

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## EXPLANATORY NOTES

The summary of the Hathi Committee Report is prepared by eliminating the details of the topics discussed in the report and also the Annexures and Appendixes given at the end of each chapter. A few Annexures and Appendixes alone are retained in the summary. But for this the Report is reproduced in the original form.

A general outline of the informations given in the original text and the titles of the Appendixes and Annexures are given in "Notes".

The paragraphs are numbered as in the original but along with this the corresponding page number of the original text is also given. For example, 13.89 indicates that this is the 13th paragraph in the particular chapter, which appears on page 89 of the original report.

It is necessary to understand a few technical terms that appear repeatedly in the report for fully comprehending the recommendations of the committee. These are given below.

### *Bulk Drugs and Formulations*

Fine Chemicals, intermediates and Penultimates are the basic chemicals necessary for the production of bulk drugs.. They also represent the different stages of the production of bulk drugs. Bulk drugs are utilised to formulate drugs, that is to prepare drugs in different forms, like tablets, capsules and injectables. The technology for formulating drugs (formulation technology) is a simple one, whereas production of bulk drugs and the basic chemicals needs sophisticated technological capability.

The technological self-reliance of a country in drug production depends upon its capacity to produce basic chemicals and bulk drugs.

### *Brand Name, Generic Name*

Generic Name is the Scientific name of a drug. Brand name is the company (trade) name. A drug with a particular generic name may be marketed by different companies in different brand names. Apart from this a drug has a chemical name also.

For example, Disprin and Majoral are the brand names of the same drug. Aspirin is the generic name of this drug and Acetyl Salicylic Acid is its Chemical Name.

The internationally acceptable generic names of drugs are published by World Health Organisation as the International Nonproprietary Names (INN).

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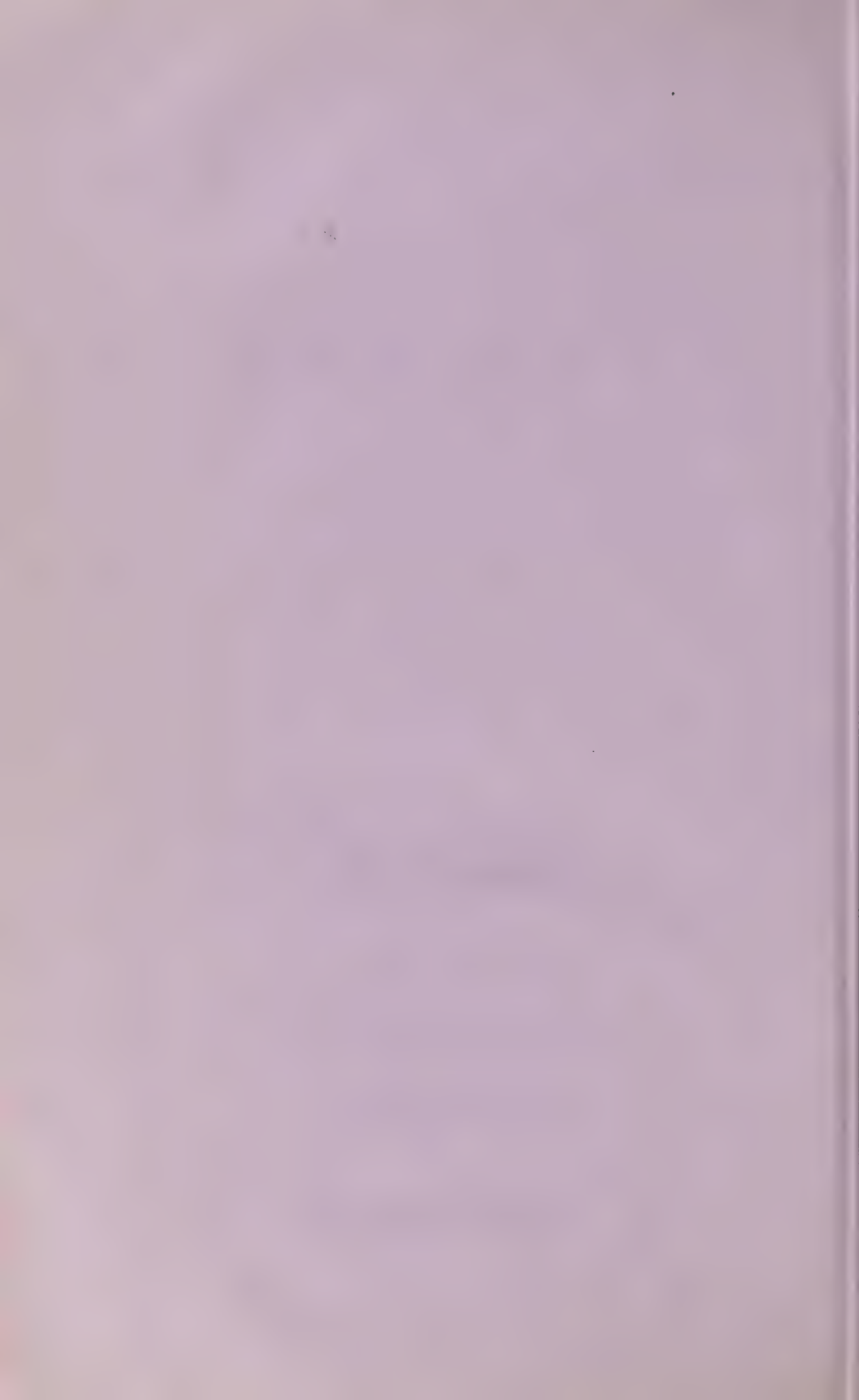
# PART ONE



## HATHI COMMITTEE REPORT



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REPORT  
OF  
COMMITTEE ON THE  
DRUGS AND PHARMACEUTICAL INDUSTRY  
MINISTRY OF PETROLEUM AND CHEMICALS  
GOVERNMENT OF INDIA  
APRIL 1975



*(SUMMARY)*

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# I

## INTRODUCTION

1.1. The functioning and growth of the Drugs and Pharmaceutical Industry in India over the past few years were engaging the attention of Government for quite sometime, particularly with a view to finding out ways and means to meet the growing requirements and broad social objectives before the country. Questions about the performance of the public sector units, multi-national firms' gaining stronghold in this field, prices of locally produced medicines, etc. were raised in the Parliament. Following a suggestion made in the Parliament, the Government of India in the Ministry of Petroleum and Chemicals set up a committee by a Resolution No.3 (26)/73-Ch III dated the 8th February, 1974, consisting of the following members.

1. Shri Jaisukhlal Hathi	Chairman
2. Shri Yashpal Kapur M.P.	Member
3. Shri Vasant Sathe M.P.	Member
4. Dr. Ranen Sen M.P.	Member
5. Shri K.S. Chavda M.P.	Member
6. Shri C.M. Stephen M.P.	Member
7. Dr. M.L. Dhar, Director, Central Drugs Research Institute	Member
8. Dr. B.D. Tilak, Director National Chemical Laboratory, Poona.	Member
9. Shri S.S. Marathe, Chairman, Bureau of Industrial Costs and Prices	Member
10. Shri Vinod Kumar, Joint Secretary, Ministry of Petroleum and Chemicals	Member
11. Shri P.S. Ramachandran, Drugs Controller, D.G.H.S.	Member

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|---|------------------|
| 12. Dr. S. Shah, Dy. Director General,<br>D.G.T.D.  | Memb.            |
| 13. Dr. B.V. Ranga Rao,<br>Centre for Studies in Science Policy<br>Jawaharlal Nehru University                | Member           |
| 14. Shri M.K. Rangnekar, Commissioner,<br>Food and Drug Administration,<br>Government of Maharashtra, Bombay. | Member           |
| 15. Dr. P.R. Gupta, Advisor (Drugs)<br>Ministry of Petroleum and Chemicals                                    | Member Secretary |

3.2 (The Committee coopted Dr. B.B. Gaitonde, Director Haffkine Institute, Bombay. Shri P.S. Ramachandran retired from Government Service and Dr. S.S. Gothoskar who succeeded as the Drug Controller of India was coopted as a member.)

1.2. The Government of India appointed the above Committee to go into the various facts of the Drug Industry in India with a view to promoting growth of the Drug Industry particularly of the Indian and small scale sectors, improve technological development, take effective quality control measures on drugs, reduce the prices of medicines, as well as to rationalise the prices structure, provide essential drugs throughout the country, and make available raw materials to the industry particularly to small scale sector, etc.

The terms of reference were as under:

(i) To enquire into the progress made by industry and the status achieved by it.

(ii) To recommend measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development.

(iii) To make recommendations for promoting the rapid growth of the drug industry and particularly, of the Indian and Small Scale Industries Sector. In making its recommendations the Committee will keep in view the need for a balanced regional dispersal of the industry.

(iv) To examine the present arrangement for the flow of new technology into the industry, and make recommendations.

(v) To recommend measures for effective quality control of drugs and for rendering assistance to small-scale units in this regard.

(vi) To examine the measures taken so far to reduce the prices of drugs for the consumers and to recommend such further measures as

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may be necessary to rationalise the prices of the basic drug and formulations.

(vii) To recommend measures for providing essential drugs and common house-hold remedies for the public especially in the rural areas.

(viii) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially for small scale sector.

5.2. The Committee finalised the various questionnaires for issue to various organisations. To the units in organised sector, Associations representing the Drug Industry, Indian Medical Association and other Specialists Organisation in the medical field. Another questionnaire was also issued to the State Governments to elicit their views/suggestions.

6.2. While the work of the committee was in progress an unfortunate andragic incident took place in Kanpur following administration of a Transfusion solution to some patients in a Hospital resulting in the death of some persons. As the question of quality of the medicine used involved in the incident, both the Government and the Committee felt that the question of quality control should be examined on a priority basis. Following the advice of the Government the Committee took up the term of reference namely to recommend measures for effective quality control of drugs and rendering assistance to the small-scale units in this regard, for immediate examination and report to Government. A sub-committee was appointed to go into this question thoroughly and expeditiously.

7.2. With a view to obtaining first hand knowledge for the operations undertaken by the various sectors of the Drug Industry and particularly to assess the problems faced by the Indian sector in expanding their drugs manufacturers and Associations and Organizations of drug manufacturing units the Committee visited the large and small scale drug manufacturing units, situated at the various places and met the representatives of the Associations.

10.3 The committee during the course of discussions particularly on the question of making the essential medicines available in adequate quantities to the wider section of the people including those in the rural areas, felt that a list should first be drawn up to identify the

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essential medicines which are required to be produced in large quantities for mass consumption. It considered that although the question of substitution of brand names by generic names in respect of the medicines marketed by the Industry was not specifically mentioned in the terms of reference for this Committee, the subject followed clearly from the other terms of reference such as reduction/rationalisation of prices of formulations for the consumers making essential drugs available in larger quantities to the general public, etc. The Committee therefore appointed a panel consisting of some of the members of the Committee and Specialists in the medical field, from all over the country. The panel consisted of the following members.

1. Dr. Ranen Sen, Member of Parliament.
2. Dr. A.B. Choudhury, Director, Calcutta School of Tropical Medicines.
3. Dr. S. Padmavathi, Director—Principal, Maulana Azad Medical College, New Delhi.
4. Dr. B. Ray Choudhury, Associate Professor of Medicine, Institute of Post-Graduate Medical Education and Research, Calcutta.
5. Dr. K.V. Thiruvengadam, Professor of Medicine and Vice-Principal, Government Stanley Medical College, Madras.
6. Dr. K.G. Nair, Director-Professor of Medicine, Head, Department of Cardiology and Radio-Isotope Unit, KEM Hospital and Seth G.S. Medical College, Bombay.
7. The Drug Controller of India.
8. Dr. V.J. Vakil, Hony. Professor, Gastroenterology, Grant Medical College, Bombay.
9. Dr. B.B. Gaitonde, Director, Haffkine Institute Bombay, Convener.

Dr. P.R. Gupta and Shri M.K. Rangnekar assisted the panel in its work.

### 11.3 The terms of reference of the panel were as follows:

1. To recommend measures for providing essential drugs and common house-hold remedies to the general public especially in the rural areas and,
2. Whether it would be in the national interest to substitute brand names by generic names and if so, the manner and extent to which this should be done.

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## II

# PROGRESS MADE AND STATUS ACHIEVED BY THE PHARMACEUTICAL INDUSTRY

1.16 The drugs and pharmaceutical industry in India is well established today. It now produces a wide range of drugs including the sophisticated ones like antibiotics, hormones, vitamins in addition to a large number of other synthetic chemo-therapeutics. This industry has an important role to play in maintaining the health of the nation and has the responsibility of meeting the expanding needs of the country. The task before this industry, therefore, is not only to produce more medicines and provide them in the required quantities but also to ensure that the medicines produced are of the right quality and would relieve the suffering of their illness at low cost.

3.16 It would be worthwhile to trace the history of development of the drugs and pharmaceutical industry in India and the stages it has

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trekked in achieving the present status. It has a long way to go to achieve the objective placed before this industry, and indeed, it has to strive hard to make the country self-sufficient.

4.16 A beginning was made in the production of medicines required under the modern system by starting cinchona plantation in the States of Bengal and Madras. Factories were set up in the vicinity of the plantation areas for the extraction and purification of quinine. Cessation of imports during the first world war years gave impetus to the industry to produce the medicines locally. A new compound urea-Stibamine was developed through local R & D activity, which was found to be highly effective against Kala-azar, a scourge which was afflicting the people much those days. The most remarkable success was achieved in the manufacture of Sera and Vaccines in the period that followed thereafter. During the second world war the local industry made further progress by producing a number of other products indigenously out of the locally available raw materials. Some industrial units also took up the manufacture of synthetic anti-dysentery drugs, anti-leprosy drugs and arsenicals. Side by side formulating activities were also increasing considerably based on imported bulk drugs and several new formulations were also developed locally. Here again, bulk of the activity was confined only to the processing of imported bulk drugs except for a few items which were produced from late intermediates. The slow progress of the local chemical industry also affected the growth of the pharmaceutical industry. Besides, the appearance of a number of synthetic drugs and antibiotics, which were developed abroad and imported into the country, also tended to change the pattern of drug use in India. The medicines that were available out of indigenous production, failed to keep pace with the competition offered by the products of imported origin.

5.16 In the year 1953 the Government of India set up the Pharmaceutical Enquiry Committee.

6.17 The Committee after detailed enquiry, made certain recommendations as to how the various aspects and problems concerning this industry should be examined and handled for its growth in the country.

8.17 The pharmaceutical Enquiry Committee also suggested that to make the production of the basic drugs economical each

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## HATHI COMMITTEE

manufacturer of pharmaceuticals should endeavour to produce as many of the basic drugs as practical from intermediates and basic raw materials in quantities sufficient not only to meet his own requirement but also to dovetail the production programme with the requirements of others in the country.

7.17 In spite of the growth and progress made so far, the Indian sector still faces competition from the foreign units and the reasons are not far to seek. It has been so because of the deeply entrenched impression created in the minds of the medical profession by the well established multinational manufacturing concerns of their products. These multinational units entered the Indian market with their vast resources with the result that the Indian sector of the industry now finds it difficult to compete with the former.

9.17. The drug industry presently comprises of 116 units in the organised sector (units registered/licensed under the Industries Development and Regulation Act 1951) and more than 2500 units in the small scale sector\*. The organised sector has 25 units with foreign equity exceeding 50% and 26 units with foreign equity of 50% or less. In the small scale sector, 9 units have foreign equity exceeding 50%, while 6 units have 50% or less of foreign equity\*\*

10.17. According to the Industrial Policy Resolution of 1956, the pharmaceutical industry can be developed both in the public and private sectors. The Government of India set up in 1954 the Hindustan Antibiotics Limited at Pimpri for the manufacture of antibiotics, the Indian Drugs and Pharmaceuticals Limited in 1961 with two drugs manufacturing units one at Hyderabad for the production of synthetic drugs and the other at Rishikesh for the production of antibiotics, with the following objectives:

- (i) to make the country self-sufficient in drugs and pharmaceuticals;

\*There are about 209 organised sector units in the drug industry which are registered with the Drugs and Pharmaceuticals Directorate of the DGTD as in January 1983. Out of these 142 units were in production. There are four Central public sector undertakings viz. Indian Drugs and Pharmaceuticals Ltd., Hindustan Antibiotics Ltd., Smith Stane Street Pharmaceuticals Ltd., Bengal Chemicals and Pharmaceuticals Ltd and Bengal Immunity, out of which the latter three had to be taken over by the Government consequent to their becoming sick in the private sector. There are over 6000 small scale units, a majority of whom exist only on paper

Editor

\*\* See Table 3 in P. Mohan Pillai's paper. Editor

- (ii) to free the country from foreign exploitation and
- (iii) to provide cheaper medicines in adequate quantity to the people.

12.19. The industry has been expanding its manufacturing activity, and the total turnover of this industry in respect of bulk drugs during the year 1973, has been estimated at about Rs.75 crores, and that of formulations at Rs.370 crores\*.

14.18. While the industrial units in the small-scale sector are mostly engaged in the production of formulations, some of the units are also producing bulk drugs, which are either formulated by themselves or offered for sale to other formulating units, both in the small-scale and organised sectors including the foreign units.

15.18 The quantum of production during 1973 of bulk drugs, which are produced both by the small scale as well as the organised units has been shown in Annexure III. It will be seen that the production of such drugs which are already undertaken in the small scale sector along with the capacities licensed or covered by letters of intent issued in favour of the organised sector units if utilised fully would take care of the estimated requirements of such drugs for the 5th plan period in many cases.

17.20. Whatever laudable progress may have been achieved by this industry so far, it is still far from meeting the requirements of the country. The progress attained so far is not commensurate with the increasing needs of the country particularly in respect of bulk drugs. Even for a number of items which are currently produced within the country substantial imports are being made. It would be seen that in respect of a number of items, while capacities have been covered by industrial licenses issued, there has been no production in respect of

\* Production of Bulk Drugs and Formulations.

year	Bulk Drug	Formulations (Rs. in crores)
1980—81	255	1260
1981—82	289	1430
1982—83	323	1600
1983—84	345	1600
1984—85	405	1837
		Editor

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certain items, while in respect of a number of others, the production achieved is much below the approved capacities. The reasons for such non-implementation or under-implementation of proposals; capacities are many, such as delay in the procurement of equivalent raw materials, poor technology, management problems, uneconomic production etc.

18.20. It has been mentioned earlier that more than 2500 units are there in small scale sector. Their production is estimated to be about 20% of the over-all turnover of the industry. Some of these small-scale units are run by technologists and they are playing an important role in the production of bulk drugs from basic stages as well as intermediates and pharmaceutical chemicals required by this industry. Such units would be able to play vital role in the future growth of this industry by taking up the manufacture of additional new bulk drugs as well as in expanding the production of existing items to help meet the future requirements of the country. The pharmaceutical industry provide a wide opportunity to this class of entrepreneurs particularly in respect of items, which involve relatively less capital investment and where technology would pose no serious problem for their manufacture. The small scale sector could then be expected to make a major break through and contribute substantially to the nation's efforts towards self-reliance. The Committee during its visits to the various parts of the country noted with satisfaction that a number of small-scale units are confining their manufacturing activities only to the manufacture of bulk drugs, without the support of formulations. It is necessary to provide adequate incentives and assistance to this sector for its growth, particularly in the field of basic manufacture.

19.20. In spite of the considerable growth attained so far by this industry a large number of bulk drugs still require to be imported to meet the present demands.

It will be seen that the following 6 antibiotics alone accounted for a total of about Rs. 5 crores.

	Rs. in lakhs
1. Ampicillin	160.69
2. Erythromycin	66.39
3. Gentamycin	42.33
4. Streptomycin	63.14

	73.59
5. Tetracycline	86.54
6. Chloramphenicol	
	<u>492.68</u>
Total	

27.23. Drugs and pharmaceuticals produced in India are now being exported to 80 countries including the developed countries like UK, USA, West Germany, USSR, Japan and others, who buy mostly the basic drugs and fine chemicals. Total exports of drugs and pharmaceuticals accounted for about 5% of the indigenous production.

32.24. While exports have gone up from Rs.2.00 crores in 1963-64 to Rs. 37.54 in 1973-74, imports have gone up from Rs.13.17 crores in 1963-64 to Rs. 37.50 crores in 1973-74. The production of finished formulations during this period increased from 120.0 crores in 1963 to Rs.370 crores in 1973. This would indicate that the industry has to strive hard to reduce the import bill through increased production.

33.24. It would be interesting to review the shares of the various drugs according to the different therapeutic groups in their sales through the trade channels.<sup>4</sup> From the data worked out on purchase records maintained by 532 chemists spread out all over India it is seen that 22% of the market share is enjoyed by Vitamins, Tonics and health restorers and haematinics while about 20% of the market share is enjoyed by the antibiotics.

**\* Percent share of different groups of drugs (1985)**

Drug Group	Sales (Rs. in crores)	Percent of total market
	249.02	21.15
Systemic Antibiotics	187.78	15.95
Vitamins and Tonics	55.40	4.70
Cough & Cold Preparations	46.78	3.97
Anti-parasites	44.29	3.76
Analgesics	38.17	3.64
Antacids		
Anti-inflammatory and anti-rheumatics	53.06	4.50
Anti TB Drugs	30.39	2.50
Enzymes	24.69	2.10
Sex Hormones	23.61	2.00

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Category of products	1969	1971	1973
1	2	3	4
1. Antibiotics	20.7	19.3	19.9
2. Vitamins	12.7	12.1	11.7
3. Cough & Cold preparations	5.7	6.0	5.5
4. Hematinics	5.1	5.5	5.3
5. Tonics & Health restorers	4.7	5.0	5.2
6. Hormones	5.1	4.8	4.8
7. Dermatological preparations	3.5	3.9	4.1
8. Analgesics	3.5	3.7	3.8
9. Anti-rheumatics	2.9	3.1	3.1
10. Anti-diarrhoeals	3.2	2.7	3.1
11. Dietetics	3.4	3.1	2.6
12. Enzymes and digestants	2.8	2.7	2.5
13. Cardio-vascular drugs	1.9	1.8	1.8
14. Anti-spasmodics	1.4	1.5	1.8
15. Psychotherapeutics	1.8	1.6	1.7
16. Ophthalmologicals	1.6	1.9	1.7
17. Anti asthmatics	1.4	1.6	1.6
18. Amoebicides	0.9	1.3	1.5
19. Anti-T.B. preparations	1.2	1.5	1.4
20. Antacids	1.2	1.4	1.4
21. Anti-histamics	1.2	1.4	1.4
22. Sulphonamides	1.7	1.5	1.3

36.25. It is well known that the drugs and pharmaceuticals industry is highly research-oriented and the key role that R&D plays in this industry cannot be over-emphasized. The need for intensive research and development work in any field of industrial activity is of utmost importance, but this is more so in the field of drugs and pharmaceuticals.

37.25. According to the present estimate, the expenditure on research and development activity incurred by the industry in India, is about Rs.4.5 crores per annum about 1.1% of the total turnover by the industry in 1973. The expenditure is woefully inadequate when looked at from the angle of total turnover by this industry, vis-a-vis expenditure incurred on R&D in the developed countries and the turnover attained. While the expenditure by any individual unit here does not exceed 5% of its turnover except for Haffkins (14%) the R&D expenses incurred by a number of units in the developed countries range between 12-15% of their turnover.

38.25. An analysis of the data from 71 pharmaceutical companies in the organised sector revealed that while 54 companies have research and development departments, the remaining 17 companies have made no investments so far in R&D programme.

### ANNEXURE III

*Production of some bulk drugs in the Organised and Small-scale Sectors vis-a-vis Fifth Plan Target.*

(Chapter II—Para 15)

Item	Unit	Total production in small scale sector	Total production in the organised sector	Total indigenous production	Capacity approved in the organised sector	Fifth Plan targets
1		2	3	4	5	6
1. Paracetamol	T	102.28	18.62	120.90	431	400
2. DCC	T	3.48	7.65	11.13	56	45
3. Halogenated-8 hydroxyquinoline	T	45.94	100.5	146.44	427.4	450
4. Piperazine & salts	T	14.04	66.53	80.57	115	118
5. Vitamin B2	T	0.558	1.21	1.768	24	24
6. Phenacetin	T	40.67	136.85	177.52	462.18	500
7. Nicotinic Acid/amide	T	29.48	101.40	130.88	1799	600
8. INH/Isoniazid	T	17.75	96.48	114.23	458.56	265
9. Oxyphenbutazone	T	0.409	7.25	7.659	12	50
10. Phthalyl Sulphathiazole	T	1.360	Nil	1.360	153.5	150
11. Diazepam	Kgs	45	..	235	5700	500
12. Ferrous Fumerate	T	43.95	..	43.95	33.2	50
13. Aspirin	T	N.A.	821.82	821.82	2450	1900
14. Phenyl Butazone	T	1.75	11.70	13.45	159	200
15. Thiacetazone	T	14.33	35.16	49.49	127.5	70
16. Salicylamide	T	0.086	21.62	21.70	120	..
17. PAS & its salts	T	N.A.	498.27	498.27	1510	1000
18. Tolbutamide	T	0.310	57.67	57.98	77.16	75

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# III

## PUBLIC SECTOR

1.54 This chapter is devoted to the second terms of reference of this committee. These terms of reference require that the committee recommends the measures necessary for ensuring that the public sector attains leadership role in the manufacture of basic drugs and formulations and in research and development.

2.54 The public sector has to play an important role in the industrial development of the country. Subject to the overall considerations of resources the programme envisages further expansions in high priority fields to fulfil this gaps and correct existing imbalances in the industrial structure to meet the social needs of the country. The Industrial Policy Resolution, 1956, takes into account the need to prevent monopoly and concentration of economic power in the hands of a small number of individuals.

3.54 The committee notes that the public sector has achieved an overall production of substantial capacity, particularly in the fields of synthetic drugs and has demonstrated the competence of this sector to handle the growing needs of the country in this highly technological intensive area of drug production.

5.54 The Committee has suggested measures necessary to make the public sector more efficient, in respect of organisational set-up, and management patterns, taking into consideration the deficiencies, difficulties and disabilities from which the public sector units are suffering at present. The committee has also suggested the areas in which the public sector should expand so that it can effectively serve

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the objectives and attain a commanding height in the manufacture of bulk drugs and formulations. Measures have been suggested to bring about technological improvements and for appropriate organisation of research and development in the field of drug industry. The importance of utilizing various public sector laboratories and institutions has also been dealt with. In view of the fact that this sector must grow in magnitude to fulfil national needs the committee has suggested the establishment of National Drug Authority (NDA) a central organisation which will lay down and coordinate the policies of manufacturing programmes, as well as the sale and distribution systems of the products produced in public sector units.

6.54 Pattern of production of the domineering units in the private sector, which consists predominantly of multinational subsidiaries or their branches or their equity partners in India indicates that the primary objective of these units is trade, based almost entirely in the economically preferable area of formulations from bulk drugs, largely imported from their principals, rather than on the production of bulk drug themselves. Government therefore decided that, in the interests of the health and well-being of the people of this country more units for the production of drugs be started in the public sector. It was perhaps felt that health care was a national charge and the ethics of production of drugs should have essentially the character of meeting national needs as distinct from trade and commercial angle.

7.54 This emphasized the desirability of the setting up of a large drug and pharmaceuticals complex in this country and resulted in the establishment of a public sector enterprise, Indian Drugs and Pharmaceuticals Limited (IDPL) where production started in 1968. Earlier Hindustan Antibiotics Ltd., Pimpri, started production in 1955.

The committee on public undertakings said in their 22nd report:

“The setting up of the drug manufacturing units and surgical instruments factory in the public sector was intended to serve the triple objectives, namely to bring down the prices by large scale production of high quality life saving drugs, to provide facilities for medical relief to the people on a mass scale in consonance with the declared objectives of the Government in this regard and finally not only to achieve self-sufficiency but also to produce an exportable surplus and earn foreign exchange.”

8.55 Despite production of about Rs. 370 - crores worth of pharmaceuticals during 1973, it is estimated that modern drugs reach only about 20% of our people. This would imply that the majority of the people, particularly in the rural areas and economically weaker sections of the society derive little advantage from the modern systems of medicines and to that extent their suffering remains unabated. This immediately throws into focus the magnitude of inadequacy of our national effort in this vital area of not only social but also economic consequences to our people. It is thus clear that production of allopathic drugs in terms of the magnitude of the needs of the country has barely begun in India and that the field is wide open for enlightened leadership to make bold efforts and take up the challenge on a national scale and meet this vital problem by proper planning.

9.55 The National Committee on Science and Technology (NCST) and the Task Force appointed by the Planning Commission have, during the last two years carried out studies of the existing product pattern in pharmaceutical and drugs industry. The committee feels that the basic data used by the NCST and the Task Force conforms to existent pattern of market needs rather than the real social needs of the country. There is urgent need to institutionalize data collection and base the national production targets in terms of the needs identified by such a system.

12.55 Formulation activity represents the high pay-off sector of the pharmaceutical industry and bulk drugs manufacture gives comparatively low profits. Inevitably therefore, entrepreneurs who enter the pharmaceutical industry usually prefer formulation activity. An analysis of the working of a number of drug manufacturing units in this country has revealed that the ratio of capital invested to sales turn over in the formulation sector averages out at about 1:2.6 with an upper limit of as high as 1:7.75. It is estimated that a purely formulation unit recovers the entire invested capital in a 2-4 year period. On the other hand, in bulk drug production, under the best circumstances, sales turn over to capital ratio does not usually exceed the 1:1 figure and in many cases in the early development stages this ratio is much lower.

13.55 It is evident, therefore, that a manufacturer whose basic philosophy is materially trade oriented, would usually try to remain

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in the formulation sector and keep the less paying basic drug manufacture at the lowest level of production priority.

15.55 It is not therefore surprising that for the past many years, foreign or foreign-equity holding companies have by and large resisted the Government suggestions to enter the basic drug production in a big way. Experience has shown that even when these units undertake the manufacture of bulk drugs, they tend to linger long at the very initial phase of manufacture of bulk drugs from penultimate or near penultimate intermediates imported often at high cost essentially from their principals abroad.

16.56 An analysis of the effort invested in the production of bulk drugs by the different sectors of the industry provides some revealing data. In 1973, the organised sector of the drug and pharmaceutical industry in India produced a total of 5300 tons of bulk drugs.

18.56 Analysis of the production of 5300 tonnes produced in the organised sector reveals that:

(i) The public sector units produced about 1500 tons of bulk drugs valued at Rs. 24 crores.

(ii) The Indian and Indian majority units manufactured 3200 tons of bulk drugs valued at Rs. 27 crores and

(iii) The foreign and foreign majority equity units produced about 600 tons of bulk drugs valued at Rs. 19 crores.

17.56 The figures for bulk drug production in the small scale sector, in terms of tonnage, are not available. However, their total production is rated at about Rs. 5 crores in terms of money value and could be estimated at about 500 tonnes including a fairly high percentage of synthetic bulk drugs. It is interesting that out of the

### \*Bulk Drug Production

Sector	Year	
	1976-77	1983-84
	(Rs. in crores)	
Public Sector	43	61
Indian Organised Private Sector	25	155
Small Scale Sector	10	74
National Sector (Total)	78	290
Multinational companies (FERA and Ex-FERA)	63	65

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production of 500 tonnes by the small scale sector only about 3% was produced by the foreign and foreign majority units in this sector and about 97% by the Indian units.

19.56 The above figures would indicate that whereas the public sector and the purely Indian and Indian majority sectors produced large tonnage of drugs of relatively lower value, the foreign and foreign-majority units operated in general, selectively in the area of low tonnage high-rupee value bulk drugs. They contributed less than 1.2% of the total production of bulk drugs in the organised sector and recovered as much as about 27% of the turn over in rupees value.

20.56 In contrast to the efforts of the various units in bulk drugs production it is interesting that a hundred and sixteen units comprising 25 totally foreign or foreign-majority equity firms and 91 other units with either relatively minority foreign equity or totally Indian units, the "organised" sector accounted in 1973, for about 296 crores (80%) of the total turn over. Over half of this was shared by the 25 firms with total foreign or majority foreign equity and other half was accounted for by the remaining 91 units including about Rs. 20 crores worth of formulations produced in the public sector. Out of the remaining 74 crores turn over (20%) 9 fully foreign or foreign majority companies in the small scale sector accounted for over Rs. 18 crores (24%) and the remaining nearly 2500 units shared between them a turnover of about Rs. 56 crores. Analysis of about 486 units in the small scale sector reveals that 260 companies constituting over 52% of these listed units, had an individual turnover of rupees one to five lakhs. These figures indicate that the large majority of the remaining over 2000 units operate only on tiny tablets or tincture makers with no showing whatsoever in the overall economics of the pharmaceuticals and drug industry.

21.56 These relative figures both for bulk drugs production and formulations, lead to the inescapable conclusion that the multinationals have not only concentrated their effort in the product of formulations but even in their minor effort in bulk drug production they have limited their activities only to low-tonnage high-rupee-value bulk drugs. It is evident that it is the Indian and Indian majority sector and in particular the two public sector units, that have made the major contribution in the critical area of bulk drug production, which constitutes the bare plank of the pharmaceutical industry.

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22.56 There are three broad areas at present under which the various drugs may be considered:

- (i) Those derived from higher plants
- (ii) Those derived from micro organisms, lower plants and animal sources and
- (iii) Synthetics.

23.56 In the order of importance, 14 plants of medicinal value are identified by the committee.

28.57 The relative importance of these plant materials needs hardly to be emphasized. These have been taken note of by the NCST: the magnitude of needs of most of these for the future have been estimated and the area of land and other facilities required for their economic cultivation have been worked out and due recommendations made by NCST.

29.57 This committee is of the view that the biologically valuable materials derived from the above plant sources are not likely to be replaced by any cheaper or less toxic substitutes in the foreseeable future. The committee therefore strongly endorses the recommendations of the NCST in this matter. The NCST recommendations indicate a large lay out of cultivable land for these plant materials. It is estimated that about 4400 hectares will need to be brought under cultivation, in stages, for some of these plants. It is necessary that acquiring land for this purpose at the state level should be appropriately incorporated in the afforestation policies and land reforms by the State Governments.

31.57 Technologies for the processing of the above plant materials for their respective end-products are already available though there is need to streamline these processes for better economic productivity. The committee notes that appropriate technological skill for all these is already available in the country.

34.58 Antibiotics account for the most important drugs derived from lower plants micro organisms. Relevant figures indicate that as at present of the total licensed capacity for bulk production for 62% penicillin (224 MMU) is in the public sector and 38% (140 MMU) is in the Indian and Indian majority sectors. Foreign and foreign majority units have not participated in the production of this antibiotic.

35.58 Licensed capacity for streptomycin (257 tonnes) in 1973 was

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shared between the public sector units (175 tonnes equivalent to 68%) and the Indian and Indian majority units (82 tonnes equivalent to 32%) foreign majority units did not participate in the production of this antibiotic either.

36.58 The total capacity for marketable tetracyclines stood at 79 tonnes of which capacity for 52 tonnes was in public sector and 27 tonnes largely in the foreign majority units.

37.58 Licensed capacity in 1973 for the production of chloramphenicol was 109 tonnes and lay entirely in the private sector.

38.58 The public sector produced about 137 MMU of penicillin accounting for about 61% utilization of the licensed capacity and the Indian and Indian majority sector produced about 111 MMU equivalent to about 79% utilization of the licensed capacity.

39.58 Production of streptomycin in the public sector amounted to about 96 tonnes equivalent to about 55% of their licensed capacity whereas the Indian and Indian majority private sector units contributed 84 tonnes representing 102% utilization of their licensed capacity.

40.58 Public sector produced about 25.0 tonnes of tetracycline and accounted for the utilization of about 48% of its installed capacity. The private sector, consisting very largely of foreign majority units produced about 65 tonnes of tetracyclines representing 40% utilization of their licensed capacity.

41.58 Production of chloramphenicol was entirely in the private sector and was of the order of 47 tonnes representing about 43% utilization of the licensed capacity.

42.58 The import for penicillin was negligible whereas there were substantial imports for the other three antibiotics. These figures indicate that with near 100% utilization of licensed capacities we should have been able to meet and even exceed our present national needs for all these antibiotics.

43.58 Recent production figures of IDPL are indicative of the realization by this unit that with appropriate care, utilization of the installed capacities can be naturally improved.

44.59 In respect of other major antibiotics, namely erythromycin

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and ampicillin which are imported to the extent of Rs.1.6 crores in 1972-73 and more than Rs.2.2 crores in 1973-74 the Committee is of the opinion that the public sector units must undertake their production also.

45.59 While reviewing the production programme of the public sector units producing antibiotics, the Committee felt that there was considerable overlap in their spectrum of products and that this contributed to some extent to their inability to concentrate and specialise on a given line of products. The committee therefore feels that the public sector units should divide between themselves, the responsibilities for the production of individual items so that they may attain the required level of specialisation and sophistication in their respective lines of effort.

50.59 In respect of slaughter house products, eg. insulin, pancreatin, trypsin, heparin etc. effort at their production is only marginal at present. Insulin is manufactured from imported pancreas in quantities of about 900 MU against a licensed capacity of 1500 MU. Estimated requirements are 3000 MU in 1978-79 and 6000 MU in 1983-84. A joint team of scientists working under the auspices of CSIR and ICAR at the Vallabh Bhai Patel Chest Diseases Research Institute, Delhi, the Haffkine Institute, Bombay and the Central Drug Research Institute, Lucknow are right now engaged in working out the production details and economics of a process for the production of insulin from sheep, ox pancreas etc. The entire work of development of these sensitive products may be allocated to the Biochemicals units at S.V.P. Institute, Delhi, in collaboration with the Haffkine Institute and other institutions where adequate facilities exist.

52.60 Sera, vaccine, antitoxins and toxoids are produced in this country in governmental institutions and in the private sector. These include vaccines against small pox, cholera, anti tetanus serum and anti diphtheria serum and anti rabies vaccines, triple antigen and polio vaccine etc. The Committee feels that the institutional centres such as Haffkine Institute Bombay, Central Research Institute, Kasuli, Pasteur Institute, Shillong, King Institute, Guindy, Pasteur Institute, Connoor etc. and the private Indian units should be strengthened to meet the domestic needs and even for export in terms of the projections for the fifth and sixth five year plans.

55.60 Because of their very nature synthetic drugs are directly derived from fine chemicals industry and depend for their production on a variety of chemicals, which in most cases are from down-stream products of the chemical industry itself.

56.60 The Indian chemical industry is still at the stage of development. The need for drugs cannot, however, be postponed and production of synthetic drugs has to go on.

57.60 The Committee noted with satisfaction that in addition to HOC and IPCL, the recovery of chemicals from coaltar at Durgapur had been undertaken on a fairly large scale. The Committee is of the opinion that appropriate units for preparing basic intermediates from the down-stream products of the Durgapur plant would help substantially in setting up of a bulk drug manufacturing unit in the Eastern Region.

58.60 The Multinational units of the drugs and pharmaceutical industry have dominated in this country in the field of synthetic drugs and by far the largest, component of their formulation activities in this area. Most of those multinational units both in the small and large sectors have concentrated their activities on the products marketed by their overseas parent organizations and have almost completely cornered the Indian market for their respective products. They have also built up enormous markets on the sale of a large variety of other formulations eg. tonics, combination of vitamins etc. Even where purely Indian units in the medium and the small scale sector produce equivalent formulations they face the greatest difficulty of obtaining the relevant bulk drugs from the multinationals but more particularly in facing high pressure and costly sales practices of the latter.

59.60 In the last few years there has been a further tendency in multinational units to introduce newer products of similar activities with marginal differences. Since such products are patented, they are usually priced high and allowed to be formulated for a period of 2 years by importing the basic bulk drugs from their principals at a high price. The Committee is of the opinion that while considering the licensing of the manufacture of new drugs developed abroad, the main consideration should be that the proposed new drug has distinct advantages over the existing range of drugs. The committee further recommends that the therapeutic character of such new

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drugs should be scrutinised by a committee of experts.

60.60 From the early days of our independence, the Government of India have been endeavouring to persuade the multinational units to produce bulk synthetic drugs in this country and share these with other formulators. Response of the multinationals during the earlier years was negative or poor. However, in recent years some of the multinational units did enter the field of bulk drugs production obviously because of the emergence of the public sector. Eventhough they were usually highly selective and chose low-tonnage, high money-value bulk items and started to manufacture these frequently from penultimate or near penultimate intermediates imported usually from their corresponding principles at high costs.

61.61 As against the poor performance of multinational units in the field of bulk drugs, the effort of the private Indian and Indian majority sector has been a great deal more impressive and satisfying. Some of these units sell their entire production of bulk drugs to formulators or share these with other formulators. There are of course several units in this sector also whose entire bulk drug production activity is limited for their captive use.

61.62 TheCommitteenoted that when public sector entered the field of production of synthetic bulk drugs in 1968 there was need to modify production technologies to conform to economic compulsions of a competing economy. The public sector has met this challenge effectively. They have revised the technology for their production of almost all the products and worked out the technology for several other products. Their initial licensed capacity was rated to produce 851 tonnes covering 16 items. The revised licensed capacity for the production of 20 bulk drugs stood at 1988 tonnes. In 1973 they produced 1212 tonnes of 17 bulk drugs. Out of this production, the public sector distributed about 600 tonnes in 1973, to other formulators. This represent about 50% of their total production of bulk drugs. This commendable performance of the public sector technologies is reassuring. It is clear that technological competence have developed to an appropriate level in the public sector to permit entrusting this sector with heavier responsibilities with confidence.

63.61 Formulation activity of synthetic bulk drugs production in public sector has, however, been at a low ebb. There is need clearly for the public sector to upscale this activity materially by increasing the range of products to include injectibles, ointments, etc.

63.86 The Committee recommends that at least 60% of bulk drugs produced by the public sector units should be formulated by the public sector industry itself. In the disposal of the remaining 40% first preference should be given to meet the needs of the Indian sector particularly small scale units.

### *Problems of public sector and recommendations*

93.64 The fact that the employees of public sector units enjoy certain privileges, should make the employees more responsible in their work and behaviour. A spirit and system of accountability to the industry and therefore to the nation must develop from top to bottom. Moreover, the management should see that the workers are increasingly involved in the functions and operations of the public sector so that they feel that they are a part and parcel of the industry and management. Bureaucratic behaviour at the top and irresponsible attitude at the lower level should be deprecated. This would generate a healthy industrial relationship which is the best way of increasing production.

95.64 In general the Committee feels that the present structure need substantial changes so as to achieve the objectives set for the public sector in terms of our socio-economic goals.

96.64 The Committee noted that even though the public sector had served to an extent to safeguard against irrational pricing by the private sector, the existing systems had not made material difference in the pattern of either the production or distribution of drugs which are at the moment governed largely by marketing mechanics. There is need to revise these to conform to our social needs.

98.64 The public sector units are facing difficulties in procurement of raw materials required for production of essential drugs. The Committee recommends that the raw materials and intermediates produced or manufactured indigenously, essentially those manufactured in other public sector units must be made available to the public sector engaged in drug production on the basis of the highest priority. Auxiliary items such as rubber caps, glass ware and packaging materials should also be available to these units on highest priority to make them more effective and efficient.

99.64 The Committee recommends that each one of the public sector units should take immediate steps to strengthen their R & D effort

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by reasonably liberal allocations in men, equipment and materials. The Committee recognize that modern R & D in this sophisticated field is expensive in terms of investments. The Committee is however convinced that a sound R & D base is the best insurance for the growth of the drugs and pharmaceutical industry.

101.65 The Committee further recommends that both the public sector units must establish the closest liaison with the other R & D laboratories such as the CSIR, ICMR, ICAR etc. and such institutions like the Haffkins Institute, the IITS, Universities etc. . The Committee feels that such co-ordination is vital for development. The Committee cannot but emphasise the need for such co-ordination by NDA.

103.65 The Committee recommends strongly that the public sector should set an example in respect of R & D in this area and must to begin with, set aside at least 5% of the net turn over for this purpose.

105.65 In respect of such essential technologies, or the high yielding strains of antibiotics producing micro organisms as may not await indigenous development, for economic reasons, the best available technology, or antibiotic producing microbial strains must be purchased on the following terms:

(i) The technology or an antibiotic producing microbial strain should, as far as possible, be the best available in the world market.

(ii) The technology or an antibiotic producing microbial strain should be purchased centrally so that it is available to all the concerned units in the public and to such other units in the private sector, as the government/NDA may identify in national interests.

(iii) Import of technology must not be linked up with import of machinery.

(iv) The technology or an antibiotic producing microbial strain may be purchased on the basis of one-time lumpsum payment or, where necessary on the following terms.

a) Royalty payment for a period not exceeding 5 years, which may vary between 2-5% of the net sale value of the bulk drugs, the quantum being dependent upon the essentiality of the drug and the intricacies involved in the manufacturing technology.

b) Lumpsum payment, to be made in instalments, the final payment to be made only after successful implementation of commercial production in India.

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The public sector is today proved to absorb any imported technology and then improve it through R & D.

106.65 Under section 100 of the Patents Act 1970, it is stated that the Central Government and any person authorised in writing by it, may use a patented invention for the purposes of the Government. Use for the purpose of the Government has been defined in section 99 of the said Act to include the making, using, exercising, or vending for the purposes of the Central Government, a state Government or a Government undertaking. Government should, therefore, under the powers vested in it, permit the public sector undertakings to use the inventions for the purposes of the Government. The effect of this will be that the mere fact that a patent has been filed or a patent has been granted will not debar public sector undertakings from manufacturing and distributing the products so patented. The Committee feels strongly that allowing the freedom to the public sector units to use desirable patents would not only constitute an exciting challenge to the scientists and technologists, to innovate and establish production technologies, ordinarily forbidden to them by patent laws, but also would obviate payment of high royalties for really worthwhile patents.

110.66 Marketing arrangements of the products of public sector is weak. They should pay greater attention to the maintenance of close liaison with the medical profession.

111.66 The Committee feels that all the pharmaceutical public sector units now in existence should have strong boards of directors consisting of more non-official members including academicians, technologists, management experts and representatives of workers/employees.

### *Additional recommendations and suggestions*

1.71 Items which are part of the approved production programme of public sector units or items in respect of which public sector has the capacity to produce should ordinarily not be licensed to private sector units.

5.71 The ruling principle for determination of prices should be that the drugs must reach the largest number of people and profitability should be limited only to ensure progressive growth of the industry

for meeting the increasing needs of the nation with its own resources.

8.71 In respect of the import of technologies concurrent purchase of equipment should be avoided. In every case of import of technology, the R & D units of the industry and their collaborators should be associated from the very beginning. This would ensure that sophistication from the stage of import upwards may be brought about indigenously. Each imported technology should be freely available to all the relevant public and Indian sector units.

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## IV

# NATIONAL DRUG AUTHORITY OF INDIA

- 0.84 The Committee believes that health care has direct relationship with socio-economic growth of the country and a welfare state should treat production, procurement and distribution of essential drugs as a social responsibility just as important as ensuring supply of food and shelter.

With a view to tackling the problem of large scale production and distribution of drugs, the Committee recommends the creation of a statutory body which may be called the National Drug Authority of India (NDA).

The NDA should perform the following functions.

(1) Continuously assess national needs for essential drugs in the context of diseases prevalent in the country.

(2) Plan, programme, co-ordinate and monitor the production of all essential bulk drugs and their formulations and lay down the relevant priorities.

(4) Plan, procure and allocate all raw materials, intermediates and accessories either through indigenous production or by local purchase or by import.

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(6) Centrally import, where necessary bulk drugs, intermediates, raw materials, equipment and accessories and distribute these to the concerned units of the industry.

(8) Recommend price maxima in consultation with the Bureau of Industrial Costs and Prices.

(9) Plan, allocate priorities and co-ordinate R & D activities by integrating all R & D facilities in men and materials that may be available at State units, state sponsored autonomous laboratories, the relevant laboratories of research agencies supported by public funds, eg., CSIR, ICMR, Indian Council of Agricultural Research (ICAR), etc. Universities, IIT and other Institutions, and encourage all these units and laboratories in all possible ways by providing additional facilities where necessary to carry out time-bound R & D programmes, giving highest priority to process innovation and upgrading of technology.

(12) Establish an up-to-date data bank for technologies, patents, R & D information etc. and act as a documentation centre and provide all relevant information to the different units of the industry.

(13) Act as sole importer of any technology, that may need to be imported, and ensure its distribution to the participating units.

In order to discharge the above and such other functions as may be relevant to the implementation of the basic philosophy of socialising drug production and distribution, the NDA should be free from day-to-day governmental interference and should have the powers to function without operational constraints.

Composition: The NDA should have a Governing Board consisting of two members of Parliament, one expert on commercial finance and business managements, two eminent technologists, a scientist, a social scientist, a marketing expert, a labour leader and 3-5 representatives of the public and Indian private sector industry. It should have a full time chairman who should be of the rank of Secretary to Government of India. He should be of proven ability as an eminent technologist or a technologist-cum-management expert with wide operational experience and social commitment.

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# V

## DEVELOPMENT OF THE DRUG INDUSTRY AND THE INDIAN SECTOR

1.86 The Committee has discussed in this chapter the third terms of reference which calls for recommendations for promoting the rapid growth of the drug industry particularly of the Indian and small scale sectors of the industry. Examination of this terms of reference in correct perspective would be greatly facilitated if the historical development of the drug industry in the country is studied and the current status of the various sectors of the industry indentified. It also requires to be considered what the expectations of the government were in the context of its various policy resolutions on the development of the drug industry, the extent to which achievements in this field conform to the expectations of Government and the imbalances or distortions that have crept into the growth of the industry either because of loopholes in the policies or their defective implementation.

2.86 It is worth recalling how within a few years after the country became independent, foreign companies built up substantial business in this country.

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3.86 Shortly after India became independent, most of the leading multinational drug companies established themselves as trading concerns. Their initial investments were insignificant compared to their turnover. They started by importing the finished drug formulations and marketing them. Later they imported the bulk drugs and got them processed into formulations as a "job-work" basis by Indian companies. All these activities were carried on without investing in factories or employing technical personnel. Thus foreign companies could remit substantial profits and build up large reserves and assets within the country for subsequent use or investment (Annexure 1).

4.86 Between 1952 and 1965 and even upto 1968 well-known multinational units and a few Indian units operating in this country received a big impetus to boost their turn over in the shape of "Permission Letters", 364 items were permitted to be manufactured by 15 leading foreign units. Four of these items were bulk drugs and the remaining 360 items were formulations many of which could have been easily manufactured by the Indian sector.

6.87 The advent of the public sector undertakings marked an important milestone in the development of the drug industry. Hindustan Antibiotics Limited and the Indian Drugs and Pharmaceuticals Limited together had an investment outlay of about Rs. 56 crores. The fields they ventured into were antibiotics and bulk synthetic drugs which are essential and required in large quantities. Yet the growth of the influence of the foreign sector on drugs and pharmaceuticals market could not be deterred.

7.87 Thus within a period of twenty years, multinational companies attained a position of dominance in the drug industry. Multinational companies had an extremely favourable climate in this country when they commenced operations. They managed for a good length of time with a meagre capital investment, pushed up the sales of their products, remitted profits to their principals abroad and built up substantial reserves. Government policy permitted payment of royalty even on drug formulations. High prices were maintained for their drugs for several years. High pressure sales techniques coupled with distribution of medical samples on a liberal scale to the medical profession was their forte. Attractively got-up medical literature and international brand names of drugs appearing in advertisements in

foreign medical journals with which top consultants in the medical profession were acquainted played their part in popularising the drugs of foreign companies. Large sums of money were spent by foreign companies in systematically training their "medical detailers" and the general tone of detailing resorted to by them was that their products contained "something plus" over products with identical composition marketed by Indian units and that the edge in their quality was the outcome of their superior expertise and international standing.

8.87 In contrast, Indian Companies were swept off their feet by the new range of drugs introduced by foreign companies. A few units in West Bengal embarked on manufacture of synthetic drugs for treatment of tuberculosis, leprosy, malaria, diabetes etc. These products did not make much headway in the market because rapport between the Indian companies and medical profession was ineffective. Besides medical services were not geared to serve the sections affected by these diseases.

9.87 More than resources and products, it was the management policy, the high streamlined recruitment and training procedures for medical detailers, the aura of super expertise that was created, the technique employed by foreign companies to persuade doctors to prescribe their drugs and the meticulous cost and economic studies of all operations carried out by them that beat the Indian companies completely and left them far behind in the race.

13.89 It is now worth considering whether the drug industry as it has now emerged, is in conformity with the requirements of the country. The fact that the drug industry has made phenomenal progress within the last two decades cannot be gain said. In 1947, drug production was of the value of Rs. 10 crores. In 1973, the gross output is estimated to be of the order of Rs. 370 crores. However, a critical appraisal of our achievements reveal many interesting facts.

(a) About 70% of the total turn over of the drugs in the country namely Rs. 370 crores belongs to the foreign sector.

(b) Out of the total turnover of Rs. 370 crores the value of tonics, vitamins etc. comes to about Rs. 70 crores.

(c) 27 years after independence 10 firms with 100% foreign equity are operating in the country. Six of these are engaged solely in the manufacture of drug formulations.

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An analysis of the drug companies holding foreign equity in issued capital is given below:

Category	
100%	10
50-99%	24
40-50%	15
26-40%	11
below 26	6
Total	66

13.90 (f) Only 19 foreign companies manufacture bulk drugs. The rest have built up their turn over on formulations many of which are common house-hold preparations which are advertised in the lay press.

(g) Foreign companies manufactured in 1973 bulk drugs worth of about Rs. 19 crores. The two public sector units together produced bulk drugs of value of about 24 crores while the Indian sector of Industry including the small-scale sector was responsible for about Rs. 32 crores. Every rupee worth of bulk drugs would produce about Rs. 3 worth of formulations.

(h) Many foreign companies are importing mostly bulk drugs and processing them into formulations. The committee recommends that foreign companies which process formulations from imported bulk drugs should be made to manufacture the bulk drugs within a specified period.

(i) The initial investment made by foreign companies is insignificant compared to the volume of the turn-over built by them.

13.92 (m) The Committee understands that the leaders of the foreign sector of the drug industry have been making statements that quality control over drugs can be maintained only by those firms which have organised research in a big way, thereby hinting obliquely that Indian firms which lag behind in financial resources may not be able to market quality drugs.

(n) In the field of drugs, it may not be so difficult to make a good formulation as it is to sell it. Neither the dealer nor the patient has any choice of his own while supplying or purchasing drugs. There may be several good products of the same drug available in the market but the patient will perforce have to buy the drug prescribed by the doctor. In the course of our visit members have had occasion to see

several well-organised Indian units, including some in the small-scale sector which have technical competence to produce high quality drugs. The representation of these firms was that adequate Government support would enable them to fulfil the needs of the country. While Government support for such undertakings is important more vital is the need for the units themselves to maintain an effective dialogue with the medical profession regarding their products, which is absent today.

(q) There have been instance where Indian companies have accomplished the manufacture of bulk drugs before the foreign companies could do so in this country. The pleas of the Indian units that the multi-national units in India should be compelled to buy the bulk drugs from the Indian manufacturers so long as their quality is accepted by the Drugs Controller (India) is still under Government's consideration. Expeditious decisions in all such cases to ban the import of the bulk drugs concerned should be taken and implemented quickly. Unless this encouragement is given, there would be no incentive for Indian companies to take up the manufacture of bulk drugs.

13.93 (t) According to the multinational companies, research should be concentrated in the parent organisation functioning abroad. Eight Indian institutions including the public sector companies and the national Laboratories maintain fairly well-organised research facilities and specialize in different classes of drugs. Six Indian firms can also be considered to have made reasonable efforts towards developing basic research activities.

Foreign firms are not interested in research on drugs for tropical diseases as the global demand for such drugs in their view will not be sufficiently economical. The current range of drugs available for the treatment of these diseases cannot be said to be entirely satisfactory. The highest priority has therefore to be accorded for centrally-directed research aimed at discovering newer drugs in these fields.

(u) The Drugs prices control order also had its impact on the growth of the industry within the last few years. In general, while foreign drug companies managed to diversify into areas where price control is not operative, eg. foods and nutritional products, laboratory chemicals etc. Indian units had to face its full blast. Their profitability progressively declined and their capacity to market new formulations of drugs particularly in competition with foreign undertakings has been seriously impaired.

14.93 Having studied the evolution of the drug industry in this country and identified the imbalances that have developed in it, the Committee would like to set forth the challenges that face the industry.

15.94 The question that poses itself before the Committee and indeed before the country is 'what change in the drug policies are necessary to fulfil the task that lie ahead of us.' A multipronged effort is called for to achieve a number of targets simultaneously. We should reduce the import bill of the country in respect of the drugs required over the next ten years, develop as far as possible the technologies required for bulk drugs and intermediates through co-ordinated research carried out at the national laboratories and the academic institutions, try to achieve a balance between foreign exchange inflow and outflow by boosting exports in a judicious manner without affecting the domestic demand adversely and lastly foster the development of a sound and ethical small-scale sector which would not only serve as feeder units for the large-scale sector but also produce all drug formulations which are essential or which have remained the monopoly of foreign companies so far. All these exercises should be done keeping in mind the twin objectives of reducing the dominant position now enjoyed by the foreign sector of the industry and rapidly building up the Indian sector.

16.94 Government's policy is against concentration of the industry in the hands of the foreign branches and large industrial group but the result achieved is just the contrary.

17.94 The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places Indian manufacturers at a disadvantage. On the contrary if the choice were between a foreign company and an Indian company, encouragement should be given to Indian companies which are technically competent. Somehow or the other, there seems to be exaggerated notions about the capabilities of foreign companies vis-a-vis Indian units.

18.95 The already dominant foreign sector would become a mighty force to reckon with in the country's economy unless certain further steps are taken to curb the dominance of multinational companies.

19.95 The Committee has no hesitation to suggest that the potentiality of foreign companies to exploit their names and

smoother the development of the Indian sector of the Industry should be blunted. A more purposeful and positive policy of helping the Indian sector should be simultaneously implemented. The scientists and technologists in the country are bubbling with a new sense of confidence and feel that they can maximise their research effort. The Indian sector has developed high grade drug formulation skills.

- 20.95 "Does the drug industry, as it has developed, fulfil the socio-economic needs of the country? If not, how should its development be oriented?" These questions were debated by the Committee. Nationalisation of the drug industry was discussed at length as one of the alternate solutions. Different views were expressed. One of the views was as follows:-

"In India in spite of the efforts to plan socio-economic growth the drugs and pharmaceutical industry like several others operates on the principles of free market economics. The Drug industry is dominated by the foreign units which set the pattern in this industry. Even in Western European and North American countries it is widely realised that the drug firms exploit the socio-psychological factors to reap high profits. It is said that the firms have reduced life to disease to be cured in these countries by their sales propagation techniques. The experience of the last one quarter of a century in India, in the operation of the multi-national drugs units reinforces these fears. This has been confirmed by the studies conducted by various international agencies also. In our country the flow of capital through the foreign units is almost nil and the accumulation of assets through their trade operations in this country is very rapid. Rarely new or novel technology is permitted to flow either free or even on payment. Most technologies that flow from parent foreign firms into their subsidiaries or partners are in fact well established all over the world for the last 15-20 years and could as well have been imported into the country without taking recourse to equity participation.

Fears that technology flow will dry up if foreign equity is discouraged or stopped is also exaggerated. Countries in which the drug industry is state-owned have not suffered on this account. They have either bought such drug technologies as they need or have been able to develop them on their own.

If indeed technology flow becomes difficult due to take-over of the drug industry, it may be a boon in disguise as it will spur greater

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national effort in these directions and develop self-reliance - a goal to which our country is committed.

20.96 We are convinced that their continued presence in this country is a powerful damper on the challenge of our achieving the technological goals of self-sufficiency and self-reliance.

It is contended that the role of multinationals can be contained by laws of the land and the powers that are available with the Government. Whereas this is so, the real point at issue before the Committee is the manner in which such Government powers have been used in the past so as to curb the activities of these companies which are not in the national interest. The Committee's findings in this regard discussed in the various chapters of this report indicate that progress in these directions has been very slow. If this process of change is to continue at the existing rate it is doubtful if the desired objective of a truly social benefit oriented drug industry will develop in the near future. A quantum change has therefore to take place in the rate of change if the desired goals are to be achieved quickly enough.

The assertion that equity participation in several cases would be the only way by which technology flow can be insured may be valid only for a very few cases. In these cases we may import such drugs but we should at the same time launch a crash programme of R&D to develop self-reliance for such drugs. The impediment to development of domestic technology due to patents in the drug field have also now been largely removed. There is little doubts that Indian scientists and technologists will develop all such technology if a concentrated effort is made and if subsequent use of technology is assured.

It is well known that the management and staff of companies with dominant multinational foreign equity holdings tend only to look overseas for most of their technological needs and often even for resolving their day to day plant problems. Even where the R&D staff in such companies propose to develop technology of their own, such initiatives are usually discouraged by their foreign collaborators and their Indian partners usually on the ground that such efforts are either futile in view of the possibilities of access of information from parent foreign companies. In such a situation there is little incentive for such companies to become self-reliant for their R&D needs. These social costs which are non-quantifiable are indeed very serious since they make our industry permanently dependent on overseas expertise and technology.

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It is glaringly obvious that the multi-national units are not interested in producing bulk drugs in countries like India. In Europe and USA the Multinational units produce bulk drugs in a spirit of collaborative relationship. In the developing countries such production is avoided by them and where this is done, the host country pays dearly for such drugs.

The multinational units operating in India produce only a small fraction of bulk drugs. The main thrust of multinational units continues to be towards capitalizing on drug formulations and non-drug items like cosmetics and luxury goods where technology and capital inputs are much lower and which permits promotion of aggressive salesmanship and brings in much higher returns on investments. These units have built up enormous assets which are completely out of proportion to their investments. Besides they have repatriated over the years large sums of money in the form of profits.

The selective attitudes of multinationals even in the field of Research and Development are dictated almost entirely by their philosophy of global trade. Indeed, their entire philosophy of building monopolies which lead inevitably to high prices and excessive profits is completely incompatible with the socio-economic needs of this country. Their capacity to manipulate is recognised throughout the world and more regulatory measures cannot curb these activities.

Basic drugs are produced in the Indian sector including the public sector, to the extent of about 90% in tonnage terms, and this demonstrates effectively the competence that has already been achieved in indigenous technical skills.

20-97 Continued presence in this country of the highly profit motivated multinational sector can but promote only the business interests of this sector. Their presence in India as a part of their global effort to capitalize on human suffering in an organised manner must therefore cease as early as possible.

We, therefore, strongly recommend that the multinational units in the field of drug and pharmaceuticals should be taken over by Government and managed by the proposed National Drug Authority. Such take over will not create any dislocation in the production or distribution of drugs.

A second view is expressed as under:

"There is a clear case for appropriate administrative action and

constant surveillance of the performance of the multinational corporation but there is no case for the take over of foreign companies in the field of pharmaceuticals. The multinational character of some of the units in this industry can be and indeed should be used for subserving national interest. It would be our national advantage to utilize the resources and technology of multinational corporations, provided these firms are made to operate in conformity with established national objective and priorities.

The question of take over of multinational units has political overtones. The economic case for take over of drugs and pharmaceutical units, however, has to be based on the advantages accruing to the community from such a step; and in this, it is difficult to make a distinction between foreign and Indian companies. If there is a case for nationalisation of drugs and pharmaceutical firms, the argument would be equally applicable to units in the Indian sector, above a certain size. There is no case for limiting the take over to a segment of the industry namely the multinational units and persuasive case has been made out in favour of nationalisation of the whole industry."

A third view endorsed the second view, but added that the size of the wholly Indian units to be nationalised should be at least with an annual turnover of Rs. 2 crores and above.

The Committee could not come to any unanimous decision though the majority of the members were of the view that foreign firms should be taken over as set out in the first view.

21-98 In the view of the Committee foreign undertakings operating in this country should be directed to bring down their equity to 40% forthwith and further reduce it progressively to 26%. The Committee would further recommend that the dilution of foreign equity as suggested above, should not take the form of dispersed holding of the shares by large number of Indian nationals. This is because such widely dispersed holding will not in any way, reduce the effective control of the foreign equity holders. In order to serve national objectives it would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly connected with the manufacture of drug chemicals or by public financial institutions or by Government itself.

27-99 The Committee is informed that branches of foreign companies or foreign companies with 100% foreign equity have been

engaged in unauthorised production of drugs. We are of the view that wherever a company is found manufacturing drugs without Government's authority penal action should be taken against them.

30-100 The Committee understands that foreign companies which are unable to secure a foothold in the drug industry in the country in terms of the industrial policy sometimes bypass the regulations by purchasing a company operating in this country and work through it. Many foreign companies have also grown up in size by operating in the small-scale sector. The small scale sector should be a prohibited area for foreign companies.

31-100 The scale of distribution of samples of drugs by drug manufactures to the medical profession is usually heavy in many cases and leads to malpractices. In order to curb these malpractices, the Committee would recommend that excise duty should be levied on drug samples distributed by manufacturers.

33-100 The prices of imported bulk drugs, and raw materials should be screened by NDA and wherever there are reasons to doubt that they are excessive, the prices should be brought down. If the directions issued by the Government in this connection are not complied with by the companies the latter should be taken over by the Government.

37-107 The Government should keep the medical profession in touch with the policies and concepts on the development of drug industry. For this purpose, NDA should have a top level committee consisting of the representatives of the medical profession, Ministry of Health, various sectors of the drug industry and state drug controller.

50-102 The Indian Council of Medical Research should concentrate its attention particularly on the discovery of newer drugs for tropical diseases.

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26. Indian Schering Lab	83,500	6.00	5.32	1973-74	414
27. Roussel Pharm	1,96,000	6.54	1.18	1973	233.66
28. Duphar Interfran	8,00,000	36.00	18.00	1973	324.86
29. Goeffrey Manners & Co.	1,000	96.00	43.00	1973	1536.69
30. Hoechst Pharm	20,00,000	175.52	87.76	1973	2172.48
31. Martin & Harris	N.A.	37.27	18.52	1973	122
32. Organon (India) Ltd.	97,54,900	97.54	47.79	1973	316
33. Suhrid Geigy Ltd.	7,20,000	260.00	123.50	1972-73	1500.51
34. Syndbiotics Ltd.	60,00,000	75.00	36.00	1972-73	313.80
35. Uni-Sankyo Ltd.	1,00,000	11.90	5.83		N.A
36. Wander Ltd.	9,70,000	15.00	6.00	1973	127.77
37. Warner Hindustan Ltd.	70,00,000	70.00	35.00	1973	699.00

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## VI

### RAW MATERIALS FOR BULK DRUG MANUFACTURE

1.146 The raw materials required for bulk drug manufacture cover a very wide field. They consist of substances of vegetable origin like medicinal plants products, of animal origin like glands and organs of slaughtered animals, a host of organic chemicals and intermediates besides inorganic acids and bases and nutrient media and solvents for the antibiotics industry. The measures for improvement in the supply of plant products have been dealt with in Chapter 3 and 7.

1.150 The Committee understands that several expert bodies have examined in detail the possibilities of setting up of facilities in various parts of the country, like modern slaughter house, facilities for collection and storage of glands, extraction of active principles etc. The Committee is of the opinion that these valuable raw materials which are now being wasted in large quantities could be used profitably for biological products, sutures etc.

2. In regard to manufacture of chemical intermediates, the small scale industries especially those set up by the technical entrepreneurs can play a very important role. Guidance from both the users of such intermediates as well as the research laboratories in the country are required in setting up units for their production. The State Governments and financial institutions who are offering special concessions to these young entrepreneurs need to be streamlined for accelerating this development.

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3. The Committee understands that the question of distribution of molasses for the production of alcohol has received the attention of Central Government but because it happens to be a state subject there have been difficulties in evolving a more rational and effective system of pricing/distribution controls on molasses which would protect the supplies for industrial use. The Committee recommends that this question should be pursued vigorously so that the essential requirements of alcohol, particularly of the chemical-based industries are met with irrespective of the fluctuations in the output of sugar and therefore of molasses.

5. Presently there is only one source for methyl alcohol. It is necessary to have an alternate source to ensure regular supply of methyl alcohol.

Valuable chemicals like Benzene and Toluene should be made available to the chemical industry and these should not be used as a fuel as is done in steel plants. Step should also be taken to ensure that in the coke oven of the new Bokaro Steel Plant where 45,000 tonnes of Benzene and the corresponding amount of Toluene can be obtained from the coke ovens should be recovered and made available to organic chemical industries.

8.151 Linking of basic chemicals with the intermediates required by chemical-based industries not yet produced in the country is a continuous process and a challenge will have to be taken up both by the industries and the R&D institutions in the country. Wherever technologies are available in this direction there should be no hesitation in obtaining the best and our efforts concentrated in improving them further. Processing a large number of imported products does not build the required chemical base even if it be by mainly Indian owned firms but on the other hand only increases our dependence on other countries. All available facilities, in this direction should be fully utilized to raise the technical base of the country.

10.151 Although it would be desirable to regulate the import of raw materials for all formulations, a beginning should be made, whereby a central agency import all bulk drugs and intermediates needed for 117 essential formulations identified by the committee. This should be done by the National Drug Authority who will also import raw materials and the ingredients required for these drugs and distribute

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the quantities of formulations that should be produced by the firms out of the basic drugs supplied to them and ensure that the manufacturers utilise them properly.

11. NDA should advise various manufacturers to regulate their production in accordance with the demand pattern and would also control the distribution of the drugs so produced among formulators. To begin with, the bulk drugs indigenously produced and chemicals required for the production of 117 items as identified by this committee should be pooled by the NDA and distributed to the manufacturers according to their requirements.

13. NDA should also look after the requirements of packaging materials like glass/plastic bottles and such other essential packing materials required by the drug industry.

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# VII

## DEVELOPMENT AND FLOW OF TECHNOLOGY

1-162 Technology, economy and social utility are very much dependent upon the scale of production, physical requirement, market capacity and Government policies. The present structure of the drug industry being one geared to the market mechanism from which vast majority of the Indian population is excluded, it cannot serve the broad social goals envisaged.

2-162 It is necessary in the Indian drug industry to identify a radically new direction to fulfil the social needs and enhance its technological efficiency. Technology is closely linked up with its social role. In the Indian drug industry, introduction of a new drug or a new process by a unit is decided on the profitability to an individual entrepreneur.

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Problem of technology in the drug industry are complex, not only due to the rigorous experiments to be conducted first in the laboratories on animals and then on human beings, but also due to involvement of various sections in the community and their interlinks in the use of drugs. In a country like India, where the average technical knowledge of the consumer is rather low and technical guidance for him is scarce, the role of Government becomes highly important. The drug manufacturing units, in general, are credited with the ingenuity and expertise to cozen not only millions of citizens, but also the Government and even the most advanced and technically powerful societies could not escape this. Unless the very activities through which such influence could be exercised are eliminated, it is difficult to bring out any marked change in the prevailing system.

4-162 Technology for the 'production of bulk drugs is closely interwoven with that needed for the production of basic chemicals. Indeed in the West, drug industry followed the establishment of basic chemical industry.

5-162 In India, chemical industry was almost non-existent at the dawn of our independence and our effort in drug production amounted really to only large scale preparation of simple extracts, and injectibles and the latter two groups were often prepared from imported materials.

6-162 Chemical industry has come a long way during the past 27 years and we have today a reasonable base to pick up challenges in this technology intensive industry with confidence. Indeed working of Hindustan Organic Chemicals Ltd. (HOC) and Indian Petrochemical Corporation Ltd. (IPCL) the Durgapur Complex and a number of units in the private sector manufacture today a large variety of chemicals based on down-stream products of coaltar distillation, molasses base alcohol, petroleum etc. There is of course need for increased productivity in a rationalised manner of all that we produce now and diversification of production to cater to national needs on a priority basis.

7-163 We have over years imported technologies for the production of important antibiotics and a number of bulk synthetic drugs both in the public and private sectors. Many of these technologies have been substantially refined by indigenous effort, for better economy in

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production. Besides, technology for several products has been developed within the country. All these challenges have been met with confidence and our base of technological competence as on date is substantial. Indeed the country is now poised not only to absorb technology of any complexity that may be imported but also to improvise and innovate production technologies with competence and complete confidence.

13-163 Stepping up production of the existing units by improvement of technology through R & D activities and efforts of the State owned research laboratories are no doubt, very important. This should not, however, preclude obtaining from abroad crucial technology for the purpose. Harnessing our limited resource of R & D facilities will definitely yield better results by concentrating on selected fields and also on improvement of imported processes. In this way, we will be able to shorten the period during which we have to depend upon imports of drugs essential to the community, maximise the effectiveness and development of domestic research and in the long run build up competence for export of technology developed by us.

14-163 Some of the advantages in following this procedure are very glaring in the field of antibiotics. With better strains and improvement of environment conditions for the growth of the micro-organisms which produce the antibiotic molecules much higher production can be attained from the existing plants.

15-163-164 With the progressive improvement of the technical base in the country coupled with any improvement in the processes obtained from abroad, several of the bottlenecks which affect production could be overcome. This along with our own ingenuity can mean a totally new process which we can even offer to other countries. It should be borne in mind that bargaining power of our country for obtaining new technology is entirely dependent on our technical base. The amount of foreign exchange that can be saved by these efforts is evident from the major imports of drugs which in many cases, are necessitated because of indigenous production (Annexure-I).

16-164 With improved technology and better utilisation of capacity not only can imports be reduced but also exports of drugs, which amount to Rs. 16.41 crores in 1973, can be increased several fold.

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Even improved technology can be offered to other countries to generate a two-way flow of technology.

17-164 Another important field where this country can take advantage of the special climate and soil condition is the scientific cultivation of plants required for the drug industry. Today there is a considerable demand for plant products in the world in spite of the advances in chemical technology and development of cheaper synthetics and antibiotics.

22-165 Research and development require large resources. We should, therefore, concentrate on mostly those drugs which are essential for diseases prevailing in our country. Some of the essential categories are:

- I) Anthelmintics
- II) Anti-leprotics
- iv) Anit-malarials.

23-165 The Committee notes that the technology for production of sera, vaccines, anti toxins and toxoids including those identified as essential drugs by The Committee has been evolved and further improved in this country. As at present there is therefore no need to import any technology for this line of endeavour.

29-165 the Committee recommends that in addition to R & D laboratories of the public sector, the following laboratories may be involved in developing these technologies, National Chemical Laboratory, Poona, Central Drug Research Institute, Lucknow, and Regional Research Laboratory, Hyderabad. Other institutions interested in this type of work may also be associated in this work.

36-167 Sufficient technological skill is available in the public sector and the indigenous private sector to carry out formulation of almost any sophistication. The committee does not therefore consider that there is need to import any technology whatsoever. The committee, however, recommends that the public sector units should set up a formulation R & D unit as early as possible.

37-167 The Committee recommends that in order to reduce dependence on import of technology in general, urgent steps should be taken to equip the public sector units of the industry as also the laboratories mentioned above, with such R & D and pilot plant equipment as may be necessary for this work.

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## ANNEXURE—I

(Chapter VII, Para 15)

MAJOR IMPORTS OF DRUGS MANUFACTURED IN INDIA  
1973-74

Product	Quantity (Tonnes)	Value (Rs/lakhs)
1. Ampilicillin .....	24.6	161.0
2. Vitamin C .....	306	113.0
3. Chloramphenicol.....	65	86.0
4. Tetracyclin .....	54	74.0
5. Analgin .....	219	65.0
6. Streptomycin Suplhate.....	52	63.1
7. Cholroqain.....	48	60.0
8. Phthalyl Sulphathiazole .....	122	40.0
9. Metronidarole .....	25.6	32.0
10. Phenyl Butazone/ Oxyphenyl Butazone.....	11.0	29.4
11. Vitamin B2.....	11.8	28.0
12. Vitamin B1 .....	27	25.0
13. Pantothenates/ Panthenol.....	33	23.0
14. Suplhamethoxy-Pyridazine .....	18.8	17.0
15. Neomycin.....	4.5	15.0
Total.....		831.5

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# VIII

## PRICING OF DRUGS AND PHARMACEUTICALS

3—137 The drug industry is highly competitive particularly in the matter of formulations, but this competition is not in terms of prices but rather in the form of persuading doctors or in the case of house-hold remedies consumers to patronize a particular brand of drug. The use of brand names as opposed to generic names enables the drug industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have at their disposal information which would enable them to compare prices of drugs which are virtually identical. Advertisements rarely mention prices and in general the medical representatives canvass the superiority of their particular brands of medicine with the doctor not on grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new or improved drug. In short, the success of the large units in the modern pharmaceutical industry is dependent mainly on their ability to develop new products raised on research and to create and sustain a demand for their product and this is done by effective selling techniques and by product adaptation/innovation with a view to help the effective marketing.

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4-174 There is some evidence to suggest that while the growth of the pharmaceutical industry over the last 15 years has been quite impressive in terms of growth output, it has been less so, if one takes into account the product composition and pricing policies of the industry. It has been brought to the notice of the Committee that according to expert medical opinion in a large number of cases the therapeutic usefulness of particular drug combinations is somewhat doubtful and indeed there are cases where the usage of pharmaceutically effective ingredients are irrational or wasteful in terms of therapeutic value.

5-174 The per capita consumption of modern drugs and pharmaceuticals in India is currently estimated to be Rs.6 per year and according to some estimates only about 20% of the population use modern drugs.

The concern about drug prices therefore really arises from the fact that many of them are essential to the health and welfare of the community and that there is no justification for the drug industry changing prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand.

22-179 While the operation of price control so far has certainly helped in preventing the emergence of very large or excessive profits by the drug and pharmaceutical industry it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with the social needs or national objectives. For instance in spite of the fact that the industry has been under some form of price control for over a decade, there are still fairly wide variations in the prices charged by different units for same or similar formulations. Even more disturbing however, is the fact that the structure of product pricing appears to have a bias in favour of greater profitability in respect of less essential formulations which are consumed by the more affluent sections.

23-179 An important element of cost which needs particular attention is the cost of packing. It has been brought to the notice of the Committee that in many instances, the costs of packing materials constitute a fairly high proportion of the costs of pharmaceutical products. In some preparations the costs of the packing materials could be much higher than the ingredients used. The Committee feels

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that greater attention should be paid than at the present to standardization and economy in the use of packing materials consistent with the protection of consumer interest. It should be assured that competitive packing is not resorted to as a sales promotion measure.

8-187 The administrative regulations and licensing should be geared to ensure that greater emphasis is laid on the production of 117 essential medicines identified by the Committee. In this area the policy objective should be to ensure that prices are fair and reasonable to the producer and consumer.

9-187 If these are accepted as the primary objectives of the regulatory framework, it seems necessary to have a certain shift of emphasis in regard to the existing regulatory arrangements including the present basis of price control. Firstly, in order to encourage the production of bulk drugs which are currently imported in significant quantities, it would be necessary to list out items which can and should be produced within the country in a specified period of time. Having identified these items, all necessary assistance should be provided to enable the industry to produce them. To the extent that the public sector and/or the wholly owned Indian units are able and willing to produce these bulk drugs, they should receive preference. As long as the country is dependent on net imports of a basic drug the existing unit or a new unit may be free to determine the selling price provided it is not higher than the selling prices of STC which are based on average landed costs of imports and handling and other charges.

10-187 In the case of bulk drugs in which production is already established and in which imports are no longer necessary, greater attention should be paid to ensure that the cost of production is kept to the minimum. It would also be desirable to exempt from price control items in which there are no imports and which in terms of total sales of the basic drug do not exceed Rs.25 lakhs annually.

13-187 The Committee has come to the conclusion that more selectivity in the systems of price regulation with a view to ensuring fair prices in respect of drugs and formulations would be desirable rather than on all drugs and formulations irrespective of their importance. As a first step the Committee recommends that the formulations based on 13 drugs as identified by the Committee for

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the purpose of generic name usage should be free from price regulation.

14-187 All formulations, other than those marketed under the generic names which have an annual all India sales in excess of Rs. 15 lakhs should be within the ambit of price regulation. If necessary Government may in exceptional cases decide to add any particular product to the list of price controlled items in public interest.

14-187 In the case of other formulations, selectivity could be (a) in terms of size of the units (b) in terms of selection of items (c) in terms of controlling the prices only of market leader in particular products, for which price control is contemplated. The Committee considers:

(I) Units having annual turnover of less than Rs. 1 crore, may be exempted from the purview of price regulations. This however should be applicable in respect of the units which come under the purview of MRTP Act.

(II) Alternatively all formulations other than those marketed under generic names which have an annual all India sale in excess of Rs. 15 lakhs (including excise duty) should be the ambit of price regulations, whether or not the total turnover of the unit is in excess of Rs. 1 crore. If necessary, Government may in exceptional cases decide to add any particular product to the list of price controlled items in public interest. The ceiling price will be determined taking into account the production costs and a reasonable return for the units which are market leaders.

(III) Another variant selectivity, which could be considered would be to identify product groups, which individually are important and which collectively constitute the bulk of the output of the drugs and pharmaceuticals industry. In respect of each items on this list it would be possible to identify the leading producers who between them account for say 60% of the sales. On the basis of the cost analysis in respect of those units, maximum prices may be prescribed and all other units may be free to fix their prices. On balance the Committee is of the view that this particular variant may be administratively simpler.

15-188 The Committee feels that the recommendation of the working group on drugs and pharmaceuticals under the chairmanship of Shri. N.N. Wanchoo, on formulation activity, under the alternative scheme of pricing may be adopted with the

revised rates of ceiling on profits to cover the recent increase in the cost of inputs, bank rates etc.

18-188 In order to ensure that the drug and pharmaceutical industry acquires adequate social content, the extension of the public sector to acquire a dominant role in the industry is very important.

19-188 The Committee recommends that high priority should be given to the building up of an information monitoring system which should provide on a continuing basis and with minimum time lags all the relevant information regarding production, stocks, costs, sales profitability, raw material availability and the emerging shortages etc. This type of information will enable Government to act effectively and quickly.

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# IX

## QUALITY CONTROL OF DRUGS ·

1-190 The drug industry has made phenomenal progress over the last 25 years. However, while quality control measures are being enforced fairly rigidly by certain states, enforcement of these measures in many states is not satisfactory. An aspect which is particularly deplorable is the tendency on the part of many states to extent special concessions to firms located in their states in making purchases of drugs without regard to the quality control measures observed by tendering firms. Such a course of action is obviously ill-advised and it is likely to endanger the health of the people.

2-190 It is the responsibility of the drug control administration, to ensure that the quality of drugs manufactured by all firms is uniformly satisfactory.

9-191 At present only the states of Maharashtra, Karnataka, Gujarat and Kerala have a full-time Drug Controller with necessary qualifications and experience in the field of drug manufacture and drug testing.

13-192 Earlier, the Committee on Drug Control which was appointed by the Government to study the existing conditions of drug control organisation in the States and make recommendations for making the control measures more effective had recommended

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that there should be one Inspector for 200 selling premises. According to this recommendation, the minimum number of Drug Inspectors that the States Drugs Control Organisation should have is about 400 against which the actual number of Drugs Inspectors in the states is 369.

14-192 The States which do not have adequate number of Drug Inspectors should be helped to expand their drug inspectorate.

14-201 The Centre should assist the states in developing and or expanding combined food and drug control laboratories by extending financial assistance to them.

21-194 Enlistment of the co-operation of the public, the members of the medical profession and other social bodies such as consumer councils, etc. in tightening drug control measures and in combating spurious drugs should engage the attention of the Central and State Governments. Today there is little awareness among the public and the members of the medical profession about the working of the drug control agencies.

15-201 In addition to the existing Central Drug Laboratory at Ghaziabad, the Centre should have three more regional laboratories, one in the south, one in the east and one in the west.

16-201 In addition, the centre should also set up a central laboratory for testing sera, vaccines and immunological products. The scheme of establishment of a central regional standardisation laboratory should be given high priority in the Fifth Five Year Plan.

17-201 The States should constitute legal-cum-intelligence cells for carrying on the campaign against spurious drugs.

19-202 Setting up of State Drug Advisory Boards consisting of medical profession, police department, social workers, the industry and the trade should be provided for statutorily. Public should also be made aware of such organisations Boards.

24-202 The facilities for screening 'New Drugs', should be reinforced by the inclusion of a medical officer with postgraduate qualifications who should be able to advise on the conduct of clinical trials with 'New Drugs'.

34-197 (c) The Central Drug Control Organisation is at present depending entirely on the veracity of the toxicity data on 'New Drug' presented to it by firms, mainly the foreign ones. There are no

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facilities for counter checking such data. Carrying out toxicological studies on new drugs will be beyond the resources of most of the Indian firms. The Central Government should therefore have a fully equipped toxicological laboratory for carrying out toxicity as well as teratology studies with new drugs in particular. The Committee understands that the Bureau of Industrial Costs and Prices had recommended the establishment of such a laboratory and had further suggested that a cess of 1% on the turn over of drug firms should be levied on the drug industry for this purpose.

34-197 (f) The 'Drug Standard Cell' for the publication of pharmacopoeia and national formulary is seriously handicapped for want of staff. This deficiency should be rectified immediately, otherwise the Indian Pharmacopoeia and the National Formulary cannot be kept up-to-date.

(h) The Central Government should have its 'publicity wing' so that suitable guidance can be given to the States/General public.

37-203 Inspection of hospital, stores and pharmacies throughout the states should be frequently done.

42-203 The states should have their own centralised arrangements for purchase of drugs.

47-204 The State Government should place the testing facilities available with their analytical laboratories at the disposal of the small scale firms on payment of prescribed fees.

48-204 The Central and State Governments should conduct special seminars, technical lectures and issue bulletins emphasising on manufacturers the various aspects that have to be taken into consideration in maintaining quality control measures.

51-204 As recommended by the Drugs and Equipment Standard Committee, the Central and State Drug Control Organisations should be independent of the Directorate of Medical and Health Services. The Centre should adopt this immediately to act as an example for the State to follow.

54-204 The general public in their own interest should be aware of the precautions to be taken while purchasing drugs. They should also bring to the notice of the Drug Control Authorities whenever the existence of any spurious drug comes to their notice.

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# X

## MEASURES FOR PROVIDING ESSENTIAL DRUGS AND COMMON HOUSEHOLD REMEDIES TO GENERAL PUBLIC, ESPECIALLY IN RURAL AREAS

In order to make the essential drugs as identified by the Committee (Appendix I) available in large quantities and at a reasonably low price throughout the country, the Committee recommends the following measures.

### Production:

256 (i) production of those medicines should be expanded or taken up in adequate quantities giving top priority for the manufacture of the relevant bulk drugs active ingredients.

(ii) The Ministry of Petroleum and Chemicals should take all such measures, which will increase the production of those drugs expeditiously. Special assistance, priority for power supply, other incentive schemes, etc. may be given to entrepreneurs preferably the National Sector who come forward to undertake production of those essential drugs. In short, if there are any impediments these should be immediately looked into and removed.

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**Technology:**

(iii) In case of some drugs, the technical know-how is already available, but there is a production short fall. More entrepreneurs should be encouraged to take up the production of such drugs. In case of those drugs for which technical know-how is not available in the country, special incentives may be given to national laboratories to develop the know-how on a time bound basis. If necessary, the foreign technical know-how may also be obtained immediately.

**Distribution:**

(iv) To make these drugs available in rural areas, the distribution system must be rationalised and decentralised. In regard to household remedies and commonly used medicines which do not require the prescription of doctors, assistance should also be sought from the postal department etc. Co-operative socceteis should be encouraged for the distribution of drugs in rural areas.

**Dispensing:**

(vii) At present, there are a number of difficulties, especially in small towns and rural areas, to establish pharmacies for dispensing drugs. To obviate these problems immediate steps should be taken to revise the present syllabus of training of the pharmacists. The pharmacy council should be approached to tailor the course to suit the needs of the country.

257 (viii) Primary Health Centres should be given adequate financial assistance for purchase of drugs, so that the rural population also gets the same quality drugs in adequate amounts as in urban areas.

8-252 The question of substitution of brand name by generic names was extensively discussed. All facets of the problem were discussed in detail.

10-253 Throughout the world and in our country as well, a medical student receives his training on drugs under generic names. In fact, in all text books of therapeutics as well as pharmacology drugs are mentioned by generic names always. In the interest of rational practice of medicine, therefore, it is in the fitness of things that medical practitioners should continue to prescribe a drug under generic name so that they are fully conscious of the type of the therapy prescribed for their patients. More often the practising physician is likely to be unaware of the active ingredients of a drug

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prescribed under brand name. Two branded products containing the same or similar active ingredients may be prescribed to patients resulting in overdosage and consequent toxicity damage to the patients' health.

12-253 To bring about uniformity in names W.H.O. issues periodically a list of non-proprietary names with the recommendations that these be adopted by national organisations.

13-253 It has often been alleged that the branded products containing the same ingredient differ to a very great extent in their prices and the products bearing generic names are decidedly cheaper. In fact, in the larger context this is not in the best interest either of the manufacturer or the patient. If the same money is spent on better standardization, quality control and Research and Development the national gains will be substantial.

15-253 Brand names have been responsible for putting up a large number of unnecessary and often irrational formulations in the market. This has resulted in excessive use of drugs particularly under the name 'tonics' containing vitamins in excessive quantities. Multiple drugs combinations in amounts far in excess of what is required result in colossal national wastage of drugs. This could be substantially reduced if the brand names are eliminated. In this respect, it is to be emphasised that the entire British Health Service runs on the British National Formulary preparations, which are by and large single ingredient drugs, rather than multiple ingredient preparations.

16-254 The medical profession has acquired the habit of prescribing branded products. This has unfortunately come out of tradition of several years and not by virtue of training in medical colleges. At no stage brand names are introduced in the medical curriculum. The brand names have a corrupting influence on the profession. A doctor more often patronises branded product and unwittingly therefore makes his patient pay more than necessary. This is a matter which the medical profession should think over seriously.

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17.254 A number of new drugs are being introduced in this country under brand names. This has a two fold effect. A company with aggressive sales promotion establishes its new product under a brand name reaps the benefits during the period the patent is valid.

After the patent period is over having established the brand names, it continues to reap this harvest much to the disadvantages of other entrepreneurs.

18.254 It is often argued that the quality of a product is assured because of its brand name and substitution of brand name by generic name will result in lowering of standards. Maintenance of quality is the responsibility of the manufacturer and it does not go with the brand name. Scrutiny of the total number of substantial, misbranded and spurious products reported by various drugs control organisations and the drug testing laboratory of the Government of India at Calcutta revealed that there are more instances of branded products being misbranded or therefore spurious. There has been no instances where a product marketed under generic name has ever been reported to be spurious. Thus, branding of products promotes a tendency to prepare misbranded or spurious products.

19.254 As long as quality control organization is properly strengthened, there is no reason to fear that a substandard product will be marketed. It is, therefore absolutely essential to achieve high standards of quality control throughout the length and breadth of the country, irrespective of whether the drugs are going to be marketed under generic or brand names.

20.254 It is often argued that bio availability is an important factor in the efficiency of a drug. The W.H.O. Technical Report on bio availability has highlighted different facts of this problem, particularly, the fact that as yet there are no established and accepted methods for evaluation of bio availability of different brands of drugs. A drug manufactured by a firm may differ from batch to batch in its bio availability. Bio availability is particularly important in the case of oral preparations and that too with respect to only a very few drugs. It cannot be denied that in case of drugs like digoxin, phenytoin etc. bio availability is important, but this has nothing to do with brand or generic names. The Drug Control Authorities will have to exercise effective control over the standards of such drugs which will need bio availability studies as per recommendations of the WHO whether these drugs are introduced under generic or brand names.

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21.254 In view of all the above considerations, it is clear that there is a strong case for substitution of brand names by generic names. In the considered opinion of the Committee it may not be advisable to accomplish this change immediately.

The medical profession has been traditionally used to prescribing drugs under brand names and a sudden shift may result in considerable confusion and difficulties for prescribing doctors.

22.254 The Committee therefore is of the view that this change over from brand to generic names be brought about in a phased manner. In view of all the above considerations, the following recommendations are made.

(a) Brand names should be abolished in a phased manner.

255 (b) A beginning should be made for a change over to generic names starting with the 13 drugs identified by the Committee. (Appendix II)

(d) All supplies of single ingredient drugs should be tendered and supplies made under generic names.

(e) All drugs other than the 13 drugs should bear labels displaying prominently the generic names. Brand names may be shown in a less conspicuous manner.

(f) New drugs should not be allowed to be marketed under brand names when first introduced into this country.

(g) Multiple combinations often containing drugs, particularly vitamins, in amounts far in excess of what is required are presently marketed in India. The majority of such combinations are irrational. There is a colossal national wastage of drugs because of such combinations. The drug control administration should immediately go unto the various combinations and take prompt measures to eliminate irrational drug combinations. New types of multi-ingredient preparations should not be allowed to be marked hereafter unless they are mentioned in the National Formulary. If any amendment of the Drugs and Cosmetics Act and Rules is considered necessary for this purpose this should be carried out.

(h) Non proprietary names as recommended by WHO from time to time should be adopted.

(i) Bio availability studies are important in cases of a few drugs, although this factor has recently been over played not always on rational basis. Facilities should be created in different parts of the country, so that the industry, both large and small scale, can take

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advantage of such facilities to plan and conduct bio availability and pharmaco kinetic studies.

(j) In order to keep the medical profession, particularly the general practitioners, well-informed about New Drugs and also to popularise the generic names it is essential to take the following steps immediately.

(i) To revise the Indian Formulary and make it upto-date.

(ii) To public journals on the lines of Prescriber's Journals, U.K., Medical Letter, USA, or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an Editorial Board comprising of the leaders of the medical profession in the country constituted by the Ministry of Health, Government of India.

23.254 The Committee is of the view that from legal point of view there should be no difficulty in abolishing the brand names. Abolishing of brand names will entail first the amendment of the Trade and Merchandise Marks Act, 1958 and subsequently the Drugs and Cosmetics Rules.

## APPENDIX I

### Tablets and Capsules (Granules Included)

1. Cap. Chloramphenicol 250 mg.
2. Cap. Tetracycline Hydrochloride 250 mg.
3. Tab. Idochlorhydroxy Quinoline 0.5 gm.
4. Tab. Nitrofuratoin
5. Tab. Chlorpheniramine
6. Tab. Ferrous Sulphate
7. Tab. Folic Acid.
8. Tab. Digoxine
9. Tab. Aspirin
10. Tab. Phenobarbitone .
11. Tab. Chlorpromazine
12. Tab. Prednisolone
13. Tab. Hexa Vitamin (N.F.I)
14. Tab. Vitamin B. Complex

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15. Tab. Vitamin C
  16. Tab. Sulphadimidine
  17. Tab. Metronidazole
  18. Tab. Hydrochlorothiazide
  19. Tab. Reserpine
  20. Tab. Glyceryltrinitrate
  21. Tab. Analgin
  22. Tab. Antacid (B.N.F)
  23. Tab. Piperazine (Syrup Piperazine)
  24. Tab. Tetrachlorethylene
  25. Tab. Tolbutamide
  26. Tab. Thiacetazone & Isoniazid (each tablet to contain Thiacetazone 37.5 mg. BPC & Isoniazid 75 mg. IP)
  27. PAS granules
  28. Tab. I.N.H.
  29. Tab. Dapsone (50 mg)
  30. Tab. Chloroquine Sulphate 0.2 gm (or Tab. Chloroquine Phosphate 0.25 gm IP)
  31. Tab. Primaquine Diphosphate (2.5 gm. or Primaquine base)
  32. Tab. Diethylcarbamazine Citrate (50 mg)
  33. Tab. Anti-asthmatic (containing ephedrine Hcl. 50 mg. Theophylline 65 mg. and Phenobarbitone 30 mg)
  34. Tablets containing alkaloids of Ergot equivalent to 0.4 mg of total alkaloids ergotoxin.
  35. Capsules of Vitamin A 6000 units and Claciferol 1000 Units.
  36. Tab. Vitamin A
  37. Tab. Vitamin D
  38. Tab. Milk of Magnesia
  39. Oral Contraceptive (approved by Family Planning Department)
- Injections.**
1. Injection Penicillin
  2. Inj. Streptomycin
  3. Inj. Emetine Hydrochloride
  4. Inj. Atropine
  5. Inj. Adernaline
  6. Inj. Nor-Adrenaline
  7. Inj. Dextrose Saline
  8. Inj. Furosemide
  9. Inj. Morphine Sulphate
  10. Inj. Pethidine
  11. Inj. Paraldehyde
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12. Inj. Prednisolone
13. Inj. Anti-Tetanus Serum
14. Inj. Methyl Ergometrin
15. Inj. Chlorpheniramine Maleate
16. Inj. Fortified Benzyl Penicillin PP (Procaine Benzyl Penicillin 3,00,000 units, Benzyl Penicillin 1,00,000 units.)
17. Inj. Aminophylline/0.5 gm/2 ml)
18. Inj. Oxytocin (Oxytocin 5 i.u./ml)
19. Inj. Chlorpromazine
20. Antivenom Serum (Polyvalent)
21. Rehydration fluid (for treatment of cholera cases)
22. Glucose Ampoule (containing dextrose 25%)
23. Distilled Water (25 cc ampoule)
24. Inj. Phenobarbitone Sodium (200 mg/ml)
25. Inj. Mepheteramine
26. Diphtheria-Pertussis-Tetanus Vaccine
27. Inj. Tetanus Toxoid
28. Inj. Diphtheria Toxoid
29. Inj. Anti-Diphtheria Serum
30. Oral Polio Vaccine
31. Inj. Insulin Plain (40 units per ml)
32. Inj. Sodium Pentathol
33. Inj. Succinyl Choline
34. Inj. Xylocaine

**Miscellaneous (Syrup, Ointments, mixtures, eye drops, ear drops, etc.)**

1. Sulphacetamide Eye Drops
  2. Homatropine Eye Drops
  3. Esserine sulfate eye drops
  4. Benzyl Benzoate Emulsion
  5. Acid Carbolic
  6. Lysol
  7. Tr. Iodine
  8. Syrup Piperazine
  9. Ext. Belladonna (Combination of Phenobarb & Belladonna)
  10. Chloramphenicol suspension (125 mg/ml)
  11. Syrup Paracetamol (125 mg in 5 ml)
  12. Tetracycline Hydrochloride Ointment 1% in sterile ointment base
  13. Gripe Mixture for infants (5 ml contains Dill oil BPC 0.005 ml; sodium bicarbonate I.P.O. 0.005 gen dehydrated alcohol I.P.0.0248 ml.(Syrup & Preservative)
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14. Syrup Noscapine
  15. Whitefields Ointment Benzoic acid 6 g; salicylic acid 32 g; alcohol 70% upto 100 g)
  16. Nitrofurazone ointment (0.2% in non-greasy ointment base)
  17. Petroleum Jelly
  18. Potassium, Permanganate 5g packets
  19. Diethyl Ether (Anaesthetic)
  20. Cetrimide Lotion
  21. Iodine Solution (Caudium Solution) for sterilizing raw catgut, loops and loop introducers (Iodine 1g. Pot Iodide 1.5 g. Distilled Water to produce 100 ml)
  22. Plaster of Paris Bandages
  23. Adhesive Plaster
  24. Ethyl Chloride (100 ml spray)
  25. Boric Acid-Alcohol-Glycerol drop (Boric Acid 1.5% Glycerol 3.3% in alcohol 95% 10 ml.
  26. Bleaching Powder
  27. Phenyle
  28. Epsom Salt
  29. Krushen's Salt (Each gram contains Sod. Sulphate Exsic 20 mg., Sod. chloride 10 mg., Pot. Chloride 10 mg., Pottassium Sulphate 55 mg., Citric Acid 45 mg., Magnesium sulphate excis)
  30. Ointment containing: Resublimed Iodine 4%, Methyl Salicylate 5%
  31. Ointment containing: Oil Eucalyptus 8%, Oil clove 1%, Menthol 3%, Thymol 2%, Methyl Salicylate 5%. Campher 5%
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Note: Drugs like Iodochohydroxy Quinoline and Analgin are included in the list since the toxicity of these drugs were not reported at the time of publication of the report.

Editor

## APPENDIX II

1. Chloramphenicol
  2. Tetracycline
  3. Ferrous Sulphate
  4. Aspirin
  5. Chlorpromazine
  6. Reserpine
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7. Tolbutamide
8. Analgin
9. Piperazine
10. Crystalline Pencillin G
11. Streptomycin
12. INH Tablets
13. Tablets INH—Thiacetazone.

(All dosage forms of above drugs by marketed under generic names)  
Chlorpromazine, Ferrous Sulphate and Piperazine and its salts. The

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**Note:**

The 1978 drug policy decided to abolish the brand names of the following 5 single ingredient drugs: Analgin, Aspirin, Chlorpronazine, Ferrous Sulphate and Piperazine and its salts. The Government also decided that no new single ingredient drug be marketed under a brand name. The drug companies obtained stay orders against the Government notification from the Delhi High Court. The Central Government moved an appeal in the Supreme Court in 1982. The appeal of the Government is still pending before the Supreme Court.

Editor

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# XI

## CONCLUSION AND ACKNOWLEDGEMENT

1-274. In conclusion we may state that the pharmaceutical industry in India, has a great potential, and given proper support, encouragement and guidance, it can meet the social needs and achieve the objectives set before it.

4-274. During our visit to various manufacturing units and the research and development institutions, we were greatly impressed by the enthusiasm of Indian scientists, research scholars and technologists.

7-274. During the short time that was available to us we have tried to analyse the problems of pharmaceutical industry and have made recommendations which would enable the public sector to attain a commanding height in the industry. We have also recommended steps to be taken to encourage Indian large and small scale sectors.

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8-274. We have recommended in our report the establishment of a National Drug Authority which should be entrusted with the responsibility of planning, procuring and producing drugs, supplying of raw materials obtaining technology from abroad, co-ordinating the work of various research and development institutions and distributing essential drugs.

9-274. This and various other recommendations made by us, we believe will go a long way in developing the pharmaceutical industry in India, through indigenous efforts. strengthening of Drug Control Organisation at the Centre and at the states will ensure quality and standard of drugs manufactured. Encouragement to and co-ordination of various R & D institutions will help the industry to equip itself with modern techology and know-how. These recommendations when implemented, we hope will in a large measure satisfy the social needs of the country. The fulfillment of these needs is imperative and we cherish the hope that Government will implement the recommendations made in this report expeditiously.

## **MAJOR RECOMMENDATIONS OF HATHI COMMITTEE**

(Chapter and para as in the original)

(1) With a view to streamlining the operation and achieving the basic objectives of producing and distributing essential drugs to the largest number of people as economically as may be possible, the Committee recommends the establishment of a National Drug Authority which should lay down and co-ordinate the policies.  
(Chapter III-para-5)

(2) Public sector should be given the leading role for production and distribution of drugs and pharmaceuticals. (Chapter III-para 6)

(3) The Committee recommends by a majority view that the multinational forms should be taken over forthwith. (Chapter V-Para 20)

(4) The Indian Council of Medical Research should concentrate its attention on the discovery of the newer drugs for tropical diseases (Chapter V-para 50)

(5) The administrative regulation and licensing should be geared to ensure that greater emphasis is laid on the production of the 117 essential medicines identified by the Committee. In this area, the policy should be to ensure that prices are fair and reasonable to the consumer. (Chapter VIII-para 28).

(6) The Committee recommended various measures for the effective quality control of drugs. (Chapter IX)

(7) Brand names should be abolished in a phased manner (Chapter X para 22 (a))

(8) Drug Control administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations. (Chapter X para 22 (g))

(9) The Indian National Formulary should be made up-to-date. (Chapter X para 22 (1)).

(10) Journals should be published to keep medical profession well-informed about new drugs and to popularise generic names. (Chapter X para 22 (1)).

## NOTES

A general outline of the information given in the original text and the tilts of the Appendixes and Annexures are given below. (Page numbers are given as in the original).

### CHAPTER—I (Page 1-16)

This introductory chapter discusses the terms of reference of the Committee and gives the list of the members of the subcommittee to report on essential drugs and the brand/generic issue.

As Annexures are given the resolution of the Ministry of Petroleum and Chemicals constituting the Committee on Drugs and Pharmaceuticals Industry (Annexure-I) and a copy each of the questionnaires prepared and issued to the different units of the drug industry, IMA (Annexure II-IV) and the copy of the questionnaire issued to the State Governments to elicit their views suggestions (Annexure V).

In Annexure VI details of the sittings of the Committee, visits to various drugs units, etc. are given.

### CHAPTER—II (Pages 16-53)

The detailed history of the development of the drugs and pharmaceutical industry in India and the stages it has trekked in

achieving the present status is traced in this chapter. Details given by the Committee that are not included in the summary include, the quantities of synthetic drugs and antibiotics produced by the different sectors of the industry in 1973, and the total imports of major bulk drugs during 1971-1974. In the Annexures given at the end of the chapter the following details are given:

Annexure I: Statements showing names of major drugs, capacities licensed, production targets, etc.

Annexure II: Bulk drug production in the small scale sector.

Annexure III: Production of some bulk drugs in the organised and small-scale sector vis-a-vis Fifth Plan Targets. (given in the summary)

Annexure IV: Production of bulk drugs from 1952 to 1973.

Annexure V: Statement showing the imports of bulk drugs during 1971-1972 to 1973-1974 which are also manufactured indigenously.

Annexure VI: Import exceeds Rs. 10 lakhs during 1973-74 of different bulk drugs.

Annexure VII: Itemwise exports of the drugs for the years 1971 to 1974.

Annexure VIII: Export during 1972 to 1974.

### CHAPTER III: (Page 58-83)

This chapter is devoted to the measures for ensuring the public sector to attain a leadership role in drug industry. It also lists the names of 14 plants of medicinal value and suggests measures to increase their cultivation. The Committee also discusses in detail measures to be taken to increase the production of specific synthetic drugs, enzymes, etc.

The Annexures given in this chapter are:

Annexure I: Recommendations of National Committee of Science and Technology on cultivation of medical insecticidal plants.

Annexure II: Licensed capacity, production and import of essential antibiotics.

Annexure III: Licensed capacity and production of essential antibiotics by individual units.

Annexure IV: Comparative production of IDPL during 1973-74.

Annexure V: Manufacture of sera and vaccines (Actual production -

1972 and Targets for the Fifth Plan).

Annexure VI: Details regarding the licence capacities, production in 1973 in public sector and the targets suggested by the Task Force.

Annexure VII: Licensed capacity, production, imports and targets of essential synthetic drugs.

Annexure VIII: Essential synthetic drugs not yet produced in the country.

Annexure IX: Additional capacity proposed in respect of essential drugs for public sector.

#### **CHAPTER IV (Page 84-85)**

In this chapter the Committee recommends the creation of the National Drug Authority and discusses its functions.

#### **CHAPTER V (Page 86-145)**

The recommendations for promoting the rapid growth of the drugs industry particularly of the Indian and small scale sector are discussed in this chapter. The evolution of the Indian drug industry since Independence and how the multinational companies maintained a dominant position in spite of the various industrial policy resolutions are discussed. The growth of assets of important units having foreign equity, list of permission/no objection letters issued, list of COB licenses, turnover of drug manufacturing firms with foreign equity exceeding 50%, remittance of drug firms with foreign equity exceeding 50%, import content in bulk drug manufacture, statement showing the name of foreign company and the bulk drug manufactured licence No, permission, letter No. and dates, report of the sub-committee on permission letters, diversification and COB licenses and excess production of bulk drugs by drug manufacturing firms, are given in Annexure I to IX. The list of industries where foreign concerns, subsidiaries and branches are eligible to participate as given in the first schedule to the Industries (Development and Regulation) Act 1951 is given as Appendix I. (Annexure I is given in the summary).

#### **CHAPTER VI (Page 146-161)**

The steps to be taken to improve the supply of the important solvents and nutrients for antibiotics and chemical raw materials for synthetic drugs are dealt with in this chapter. Specific measures to be taken to improve production of chemicals based on alcohol, coal and

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petroleum are given. From Annexure I to VII, requirements of raw materials for the manufacture of Antibiotics for achieving targets for the year 1978-79, requirements of important intermediates and chemicals, Ethyl alcohol based chemicals, methane and methyl alcohol based chemicals, coke oven products and their derivatives, petrochemical reformers and drug intermediates are listed.

## CHAPTER VII (Page 162-172)

Measures to attain technological self-reliance in drug industry with the available indigenous resources are discussed. Production target for 42 basic drugs by the end of the Fifth Plan, major imports of drugs manufactured in India, and the inorganic chemicals for the essential drugs produced in India are given as Annexure I-III. (Annexure II is given in the summary)

## CHAPTER VIII (Page 173-188)

The Committee here assesses the impact of the various measures taken so far by the Government to control the prices of drugs, including the Drug (Display of Prices) Order 1962, Drugs (Control of Prices) Order 1963, Drugs Prices (Display and Control) Order 1966 and the Drug Prices Control) Order 1970. The Committee also examines and comments on the main recommendations of working group on drugs and pharmaceuticals under the Chairmanship of Shri N.N. Wanchoo.

## CHAPTER IX (Page 189-250)

The full report of the sub-committee on quality control of drugs is given as Appendix A. The recommendations of the sub-committee are accepted in toto by the Committee. A note on the manner in which the public can co-operate and assist the Drug Control Organisation, set up of the drug control organisation in the states as on 1-1-1974, position regarding drug inspectors in the states, broad details of the scheme to be implemented in the 5th Plan in the different states, a summary of the recommendations for strengthening drug control and enforcement wing in states, a statement of proposed amendments to the Drugs and Cosmetics Act, note regarding the procedure adopted for purchase of drugs for Government hospitals and semi-government institutions in Maharashtra State, a manual on the working of Hospital Stores, illustrative list of drugs requiring storage at cold temperature of 2 to 10°C and 15° to 25°C, prevention and treatment of penicillin

reactions and a list of 29 life saving drugs are given in the Annexures and Appendixes of this chapter.

#### CHAPTER X (Page 251-273)

The Committee has set up a panel of experts to recommend the measures for providing essential drugs to the general public and to examine the brand/generic issue and the report of this panel was adopted with some modifications. The report of the panel is given as Annexure I.

A revised list of medicines which in the opinion of the Committee are extensively used in medical practice is appended as Annexure II. The 13 drugs recommended by the Committee to be marketed only under generic names are listed in Annexure III. (Both Annexure II and III are given in the summary)

#### CHAPTER XI (Page 274)

As concluding remarks the Committee reiterates its view that the pharmaceutical industry in India has a great potential and hopes that the recommendations made by the Committee will go a long way in developing the pharmaceutical industry in India. The Committee also acknowledges with thanks the assistance and support received from various institutions and individuals.

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# PART TWO

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**REPORT OF THE HIGH POWER COMMITTEE ON  
HEALTH SERVICES (THE PAI COMMITTEE)  
CONSTITUTED BY THE GOVERNMENT OF  
KERALA 1979**

**PROCUREMENT AND SUPPLY OF DRUGS**

*(SUMMARY)*

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### **PRESENT SYSTEM**

One of the much felt defects noted in the medicare set up is the quantitative as well as qualitative inadequacy of drugs at all levels. The present system is defective at the levels of indenting, purchase, distribution and prescribing. Indenting is not done in a rational need based manner. There is no scrutiny of indents at the concerned institutions as well as at higher levels to correct anomalies. Supply and distribution are often irregular and incomplete and never done in time. This causes terrific shortages and the medical officers are forced to improvise which in turn results in depletion of other items and distorts the entire stock position. Distribution to peripheral institutions is insufficient. Vehicles for supply is often not road worthy. Most patients have to buy drugs from the market as doctors have no other way but to issue outside prescriptions. Out-patients are given only a limited range of drugs to take home, leading to unnecessary admissions for conditions which could very well be treated at out-patient Departments.

#### **Iatrogenesis and Mediflation**

Many drugs available in the hospitals are expensive, non-essential, of unproven value or irrational and sometimes hazardous combinations. There is widespread tendency to over-prescribe and to use expensive alternatives. The Kerala State Drugs and Pharmaceuticals Limited (KSDP) is under utilized.

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A detailed analysis of the orders palced by the Director of Health Services (1975-1978) indicate that the average value of drugs ordered per year works out to be about Rs. 4.5 crores.

The following changes are recommended aiming at a state where adequacy of ordinary drug is ensured all times for treatment of the most common diseases of the community.

### **Drug lists to hospitals at different levels**

Medical officers at each level are given lists of drugs that they can indent for. They will not ordinarily be entitled to indent for any other item but can use their discretion and financial powers to effect local purchase for which respective institution is entitled to. Freedom of prescription has to be tempered with discipline.

Proper up-keep of O.P. and I.P. Registers is essential to arrive at an idea of the morbidity pattern in each area. Registers and forms necessary should be made available. Even it be provisional diagnosis both O.P. as well as I.P. be made mandatory and be recorded legibly by the the medical officers concerned.

In purchase of drugs the Committee feels that the account should be on common essential and inexpensive drugs. A Government medical institution should never be in lack of these essential drugs and allied items.

### **Role of KSDP**

The KSDP should be so expanded and tuned to the needs of the State that they will be able to supply most of the drugs required by State Health care systems. It should be clearly understood that this is the real function of the KSDP.

### **Hospital Formulary**

Prescribing habits of doctors will have to be gradually changed. A State Hospital Formulary shall be produced. All prescriptions in Government institutions will have to be within the bounds of the Formulary. If any exception is made, the medical officer will have to record his reasons for non-confirmity. All drugs in current use, thir strength, their dosage, side effect, cost and interactions should be given in the formulary. The drugs shall be listed by their pharmacological names.

### **Lists of Drugs primed**

After consulting the reports of WHO on selection of essential drugs and the 117 essential items recommended by the Hathi Committee, the list of drugs to be made available to Government

institutions has been recast. The number has been primed considerably. Modern trends have been taken into account in deleting several items and adding new ones.

### Recommendations

To fight out the modern trends of iatrogenesity and mediflation medical officers at large should be inculcated with prescribing habits through continuing education and periodic news letters.

\*Drugs should be grouped as Essential Drugs, Routine Drugs and Special Drugs and while ensuring all institutions with essential drugs, the intermediate institutions be ensured with the essential as well as routine drugs and the referral institutions with essential, routine and special drugs.

\*The KS DP should be made the kitchen for the Health Services and it should be given priority in the manufacture of medicines which are in need for Kerala Health Services.

\*The KS DP should be expanded and tuned to the needs of the State so that they will be able to supply not only drugs but also ancillary essential items of chemicals such as those needed for laboratory, Blood Bank and X-ray.

\*The State Hospital Formulary should be produced and issued free of cost to each Government medical officer.

\*There should be more frequent and rigid quality control of drugs purchased and distributed by the Health Services through the agents of the Drug Controller with better liaison and follow-up by the Health Services Authorities.

### NOTES

1. In Appendix I to III are given the lists of drugs identified as Essential Drugs by the Committee.

Appendix I—Abundant supply of drugs and materials.

Appendix II—More drugs for O.P.

Appendix III—Emergency Drugs.

2. In Appendix IV and V are given routine drugs that are needed in addition to the above in intermediate institutions.

Appendix IV—Drugs for dispensaries and primary health centres.

Appendix V—Drugs for Taluk Hospitals/District Hospitals.

3. In Appendix VI is given special drugs mostly used in specialised institutions and in speciality clinics.

Total No. of drugs given in Appendix I to VI is about 200.



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# PART THREE

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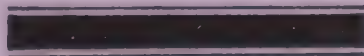
SEMINAR PAPERS



INDIAN DRUG INDUSTRY  
A DECADE AFTER HATHI COMMITTEE

ALL INDIA SEMINAR ORGANISED BY  
KERALA SASTRA SAHITYA PARISHAD  
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# **Indian Pharmaceutical Industry A decade after Hathi Committee**

**P. Mohanan Pillai**

The pharmaceutical industry in Indian has provoked much debate and sharp criticism, on account of its insensitivity towards the health needs of the Indian people. The vulnerability of the industry towards the manipulations of multinational corporations, has added another dimension to the discussion. The Government has been interfering with the working of the industry from time to time. Through regulation and control, it hoped to effect national control on the internally oriented product structure in the industry. This paper attempts to make an enquiry into the response of the industry under the impact of major policy interventions, following the Hathi Committee report which was released a decade back. An attempt has also been made to examine the likely impact of the New Drug Policy announced by the Government recently.<sup>1</sup>

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The report of the Hathi Committee constituted, perhaps, the first ever scientific attempt to understand the deep seated structural maladies affecting the Indian pharmaceutical industry. It made recommendations of a radical nature, so as to synchronise the production of the industry, with the health needs of the people. The committee looked into the entire drug scenario-production pattern, ownership control, pricing, quality control etc. The major recommendation of the committee was to evolve a system which would (1) develop self-reliance in drug technology (2) provide a leadership role to the public sector (3) aim at quick self-sufficiency in the output of drugs (4) foster and encourage the growth of the Indian Sector (5) ensure that drugs were available in abundance and at reasonable prices and (6) keep a careful watch on the quality of drugs produced.

In the attempt to remove the structural maladies afflicting the industry and to realise the objectives it has outlined, the committee recommended restrictions on the activities of the foreign sector in the short run and the nationalisation of that sector in the long run. Thereby, it hoped to pave the way for the complete control of the industry by the public and the domestic, private sectors.

Since the Hathi Committee went against the vested interests of the Multinational Corporations and their Indian collaborations, there was intense lobbying for about three years, not to implement its recommendations. However, the New Drug Policy which is claimed to have been based on the Hathi Committee report was announced in 1978. It is significant that the Government did not accept the report in its totality; the incorporation of the Committee's recommendations in the new policy was in bits and pieces and in a somewhat diluted form. A review of the major recommendations of the Hathi Committee and an appraisal of the extent to which they have been incorporated in the policy framework viewed against the response of various segments of the industry to these measures would hence be timely.

### **The Increasing Dependence**

One of the primary concerns of the Hathi Committee had been the pharmaceutical industry's external dependence. It is natural for us to expect that the overall dependence of the industry should have reduced after the implementation of the New Drug Policy and other measures. Unfortunately, the facts belie this expectations. The

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dependence is no lower now, than a decade ago. This point can be illustrated with reference to the import dependence of bulk drugs. The ratio of bulk drugs import to domestic production was continued to grow unabated (see Table I).

**Table I**

Sector-wise pattern of bulk drug, formulation production, import content, bulk drug used for the formulation of essential drugs etc. since Hathi Committee  
(Rs. crores at current prices)

Year	Sectoral share in total production (%)			Total (Rs.) crores)	Import of bulk drugs (at CIF prices)	Import as % of production	Total formulation	Of which formulation of essential drugs
	P.S.	I.S.	F.S.					
1975-76	33.08	26.92	40.00	130	46	35.38	560	n.a.
1976-77	34.28	20.71	45.00	140	84	60.00	700	n.a.
1977-78	28.66	31.71	39.63	164	81	49.39	900	n.a.
1978-79	24.50	47.50	28.00	200	95	47.50	1050	n.a.
1979-80	26.11	50.44	23.45	226	87	38.49	1150	n.a.
1980-81	26.25	51.67	22.08	240	105	43.37	1260	360
1981-82	25.51	52.38	22.11	294	115	39.12	1430	400
1982-83	26.80	65.20	17.00	325	123	38.00	1660	430
1983-84	26.00	57.20	16.80	345	178	51.59	1660	466
1984-85	—	—	—	405** (816)	n.a.		1840** (2450)	

P.S. Public Sector; I.S. Indian Sector including small scale sector;  
F.S. Foreign Sector.

Source: Ministry of Petroleum, various reports.

\*\* Estimated figures in the bracket indicate targeted production by the end of Sixth Plan.

A very interesting aspect emerging from the Table I is that of the Rs.1660 crores worth of formulation produced in the country by 1983-84 only 28 percent was used for formulating essential drugs. The rest went for the preparation of non-essential formulations. Another point to be considered is that the industry's performance falls behind by one half the targeted output of the Sixth Plan.

Table II gives the details of the growth rate of output patterns (basic drugs and formulations) between the period 1973-83. The

growth of bulk drug production after the introduction of the New Drug Policy, 1978, fell to a bare 1% from 12% at constant prices. The performance of the formulations sector was, however, better, leaving far behind the production of the bulk drugs sector.

**Table 2**

Annual Average Compound Growth of Domestic Production of Bulk Drugs and Formulations in Percentage at Current and Constant Prices.

Period	Bulk Drugs at constant prices	Bulk Drugs at constant prices	Formulations at constant prices	Formulations at constant prices
1	2	3	4	5
1973-74	22	12	25	18
1977-78				
1978-79	13	1	11	4
1982-83				
1973-74	18	8	18	12
1982-83				

Note: The prices were deflated by using Chandok Wholesale price Index—bulk price (1970=100) formulations (1970=100)

The aggregate bulk formulation ratio does not reveal in full the extent of dependence. It is significant to note that the dependence is ever increasing in respect to essential therapeutic categories like antileprotics and antimalarials. We are importing several times more than domestic production in certain essential categories of medicine.<sup>2</sup> It is evident that the restructuring of the industry, in terms of the 1978 Drug Policy (though it was based on certain recommendations of the Hathi Committee), was incapable of making the industry compatible with the health needs of the Indian people.

The reasons are not far to seek. The Committee had demonstrated in its report, that the pharmaceutical industry in India, will only perpetuate human suffering unless the MNCs who promote their global business interest are cut to size. Therefore, the Committee had recommended that the MNCs in the field of drugs

and pharmaceuticals, should be taken over and managed by the National Drug Authority—a proposed statutory body which would take on the responsibility of large scale production and distribution of drugs. The NDA would assess the national needs of essential drugs and plan and co-ordinate responsibilities with individual production units. But this critical element in the planning process of the pharmaceutical industry was set aside by the Government. Instead, the emphasis was mostly on interim measures like equity reduction, without providing a support system to ensure that such measures add to the ultimate objective of self-reliance. Even these interim measures suggested by the Committee were diluted, thereby defeating their very purpose. For example, take the case of reduction in the equity share capital according to the New Drug Policy announced by the Government in 1978. The recommendations of the Hathi Committee in this regard were diluted. The Hathi Committee had wanted the equity holding of foreign companies to be reduced to 40 percent forthwith and a further progressive reduction to 26 percent. But, as per the 1978 Drug Policy, foreign companies, which are engaged purely in formulation activity, only need to bring down their equity to 40 percent. It further adds that those companies engaged in the manufacture of high technology bulk drugs and their formulations could retain a higher equity share. As a result, the foreign sector continues to exercise its control over the industry notwithstanding the dilution process.

### **The Foreign Sector**

It is doubtful if the dilution of foreign equity leads to a dilution of foreign control. This is a different question which we shall discuss later. The administrative procedures defining exemption on the basis of 'high technology' took such a long time (as long as five years) that it rendered greater manoeuvrability to the bureaucrats and technocrats who were influenced by the tempting arguments and lobbying of the foreign companies. The outcome was that out of 44 majority owned foreign companies, 32 were exempted from the dilution of equity upto 40 per cent by 1981-82 (see Table 3). But interestingly enough, the recent trend is towards dilution of equity on their own. This trend indicates the advantage of indigenisation which we shall discuss later.

Regarding the settlement of high equity, it is interesting to note that the criterion of 'high technology' is dubious,<sup>3</sup> for, the products

identified as high technology are already being produced by fully owned Indian companies with indigenous technology.<sup>4</sup> Interestingly, such bulk drugs constitute only a small proportion of their production. As a result, even those companies involved mostly in making bandages or calcium compounds of dubious value or tableting imported tranquilisers have been permitted to retain higher than 40 percent foreign equity.<sup>5</sup> Having 'become' high technology, the MNCs throttled the very vitality of the pharmaceutical industry by cutting back the production of bulk drugs in the guise of unremunerative prices. This resulted in the heavy import of bulk drugs from parental sources, thereby increasing the scope for transfer pricing and other unethical practices. The case of Hoechst is illustrative of this point.

The imported Baralgin Keton was selling at Rs. 23,625/kg. till 1977. The government later fixed the price of this at Rs. 1810-20/kg. with effect from 31st December 1980. Before the prices of various formulations, based on the revised prices of drugs as announced by the government, could be fixed, the Delhi High Court granted a stay to the company, by virtue of this, it was able to maintain a pre-revised price for bulk drugs, under the Drug Price Control Order of 1979. The government has filed a special leave petition and application for a stay against the Delhi High Court judgement in the Supreme Court. Meanwhile, the company had made a total bulk and associated imports to the tune of Rs. 3.13 crores between 1980 and 1984 and remitted Rs. 2.08 crores during the above period.<sup>6</sup>

No wonder then, that the stipulation regarding the manufacture of bulk drugs made by the Hathi Committee, remains a far cry even after a decade. The Committee was of the opinion that a foreign undertaking producing formulations, should start and complete manufacture from the basic stage, within a period of three years, failing which it should not be allowed to continue marketing the formulations. And, those foreign companies producing more than their licensed capacity, should be made to part with 50% of this production to non-associated Indian formulators.

In the New Drug Policy of 1978 the 'high technology' qualification was more or less an excuse to the first stipulation of manufacturing from the basic stage. Not only did the foreign companies keep the bulk production from the penultimate stage, but

Table-3

**Pattern of Share Holding of Foreign Companies  
Since Hathi Committee**

Company Type	Non-resident share in foreign equity	1975-76*	1981-82**	1984***
FERA Companies	1. Above 74	20	5	3
	2. 50 to 74	11 41	14 32	10 14
	3. Above 40 and upto 49 10		13	1
Non FERA Companies	4. Between 26 to 40	10	13	30
	5. Below 25	10 20	13 26	12 42
Total		61	58	56

\* Drug Prices and costs of production, Economic Times, November 15-16, 1977.

\*\* Indian Drug Statistics, Ministry of Petroleum, 1978, 1982.

\*\*\* Compiled from various issues of Assochem Parliamentary Digest.

the Government also subsequently permitted them to make use of the import of bulk drugs, even under concessional duties<sup>7</sup> (also see Table 4). The Government by the Drug Policy of 1978 also permitted the foreign companies to share half their unauthorised drug production with any non-associated firms. This only helped the collusive strategy of the MNCs in the pharmaceutical industry! Therefore, the original intention of the Hathi Committee to check the strength of the MNCs in the Indian formulation market was defeated by the new policy. Again in 1980 decisions were taken according to the new industrial policy to regularise the "excess capacity" of formulations produced by foreign companies. Although, the Government, by the drug policy of 1978, fixed a very liberal bulk formulation ratio of 1:5, the ratio was 1:12 as on 1982-83 (See Table 5).

### Foreign Sector in Disguise

We were discussing above those companies which did not undergo the Indianisation process of 40% and below. It is true that there is no magic in the rule-of-thumb formula of direct non-resident ownership upto 40 per cent, which will reduce the extraterritoriality of control. In fact, it is not possible to fix precisely any particular ownership proportion as the criterion of measuring the actual

Table—4

Names of the Multinational Drug Companies Operating in India along with the Drugs being Manufactured by each of them from Penultimate/intermediate stages

Sl.No.		Bulk Drug Produced from Penultimate Intermediate stage
I.	M/s. Alkali Chemicals Corporation (P) Ltd.	1. Primidone 2. Halothane 3. Chlorohexidine
II.	M/s. Bayers	1. Chloroquin Phosphate 2. Rosotreu Substance (Chloquinatone) 3. Detigon Substance (Chlorphedianol base) 4. Incidal Substance (Mebhydrotin) 5. Badional 6. Uvilon (Piperazine Phosphate)
III.	M/s. Pfizer Ltd.	1. Chlorpropamide
IV.	M/s. Roche Products	1. Vitamin E Acetate 2. Chlordiazepoxide
V.	M/s. Sandoz (I) Ltd.	1. Intestopan Substance
VI.	M/s. Wyeth Laboratories	1. Ethopheptazine Citrate

Source: Assochem Parliamentary Digest, April 1985.

control exercised by foreign companies in Indian enterprises. It all depends on who holds the rest of the 60 per cent shareholding and how widely this is held. Above all the precise terms of the contract for

Table—5  
Ratio of Bulk Drugs to Formulations

Sectors	Ratio as on 1974-75	Ratio as on 1980-81	Ratio as on 1982-83
I Foreign Sector	1:6	1:12.53	1:12
II Indian Sector	1:8	1:2.6	1:3.44
III Public Sector	1:0.8	1:1.26	1:1.12

Source: Same as in Table I

HATHI COMMITTEE

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technology are important. The Hathi Committee, in fact, considered this aspect and indicated that equity should not be shared widely among Indian nationals, but should be purchased by, public sector institutions which are connected directly or indirectly with the manufacture of drugs and chemicals or by public financial institutions or by the government. But, contrary to this stipulation, no safeguard was taken while dispersing the equity of foreign companies and hence, they dispersed it as widely as possible, to subserve their main interest of retaining control in their own grip. According to the latest figures, there are 43 companies, whose equity is 40% and below. More firms are likely to dilute to 40 per cent.

Indianised thus, the government made them immune to the basic requirements stipulated by the Hathi Committee, which said that (1) foreign companies should be allowed to manufacture household remedies such as alcohol based tonics, vitamin preparations, ointments for colds, burns, **apirin** tablets etc. (2) foreign units which were already engaged in the manufacture of these household remedies should not be granted any expansion of capacity and (3) remittances of money outside this country would be permitted subject to certain conditions like the fulfilment of export obligation and other commitments imposed in the licence by a body created specially for this purpose. The Hathi Committee hoped that these restrictions coupled with indigenisation would bring foreign firms within the ambit of the overall strategy for increased production and would prevent a further foreign exchange drain from the country.

But a mechanical view of the process of indigenisation without **monitoring led to disastrous** consequences to the industry. Having escaped from FERA's grip these companies have expanded their formulation capacities<sup>8</sup> into low technology areas. This kind of expansion has been in contrast to the Hathi Committee recommendation that additional formulation capacity, if necessary, should only be permitted either to public sector units, units sponsored by state governments or in the purely Indian sector units run by technocrat entrepreneurs.

That the expansion of capacity has not taken place in desirable areas, tells upon the scarcity felt in essential categories of formulations in recent years. We shall go into this issue later. One only has to look at the high remittances to parent companies which

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reflect upon the high profitability of their operations out of new expansions. We have compared the remittance pattern (at current prices) of these companies before and after the dilution of equity. Clearly some companies have managed to send out eight times more to their parent companies than they could before Indianisation (Table 6). Overall, with the lapse of seven years, the remittances have more than doubled. Table 5 clearly brings out the cost to the country due to unwanted "expansion" in the guise of Indianisation. There are indications that the foreign companies retaining more than 40 per cent at present will further reduce equity to enjoy the advantages of Indianisation.

### **Control on Production**

Did the pervasive influence of the MNC's diminish in the pharmaceutical market over a period of time by the so called structural transformation in the form of indigenisation of the industry? As the production statistics relate only to majority owned foreign companies, we cannot estimate the full production share of the foreign sector (including Indianised foreign companies). Even the practice of giving sector-wise production figures by official sources was discontinued since 1980-81. Attempts at sectoral estimates showed that in the dynamic expansion of the market for pharmaceuticals, foreign companies could carve out a disproportionate share from the other sectors.<sup>9</sup> At the time when the Hathi Committee submitted its reports, the 34 majority owned foreign companies had a share in the formulation production to the extent of 40.17 per cent. By 1983-84, around 14 companies could control 39% of the formulation market (615-1600). This does not include the share of another 20 companies that have foreign equity upto 40 per cent. They added 25 per cent more to the foreign control. Thus 64 per cent of the formulation market clearly belonged to foreign companies.<sup>10</sup> If the share of companies having above 10 to 15 per cent equity is also added it may not be surprising if the total share of the entire foreign sector in formulation production exceeds 75 per cent. It is interesting to contrast this to the estimates of the Government in 1978. Assuming a 1:5 bulk formulation ratio for the foreign sector, the share of formulation production was expected to increase only by 47% of the total formulation market by 1982-83.<sup>11</sup> Ironically enough, by 1981-82 when the total bulk production lagged behind by half (Rs. 275 crores against 500 crores projected for

## HATHI COMMITTEE

1983) the foreign sector nearly achieved its targets by 1980-81 with a bulk drug formulations ratio of almost 1:12. The real control over the formulation market can be studied by the MNC's domination in the therapeutic categories. The information on this available from ORC estimates of 1977-78 of retail sales showed a high degree of concentration.<sup>12</sup> This changing dimension may be another area of interesting study.

Table—6

## Remittances of Indianised Companies

Average outflow on account of profit, technical fees, royalty etc. (Rs. lakhs)

Company Code	Foreign equity before dilution	Annual average outflow (71-73)	Foreign equity after dilution	Annual average outflow (80-82)	Percentage increase
A	63	50.72	40	150.38	196
B	72	63.90	40	135.58	112
C	53	54.89	40	108.77	98
D	62	25.49	40	105.81	315
E	70	72.12	40	102.10	30
F	56	8.30	40	40.21	303
G	49	4.32	40	40.10	828
H	45	3.12	39	14.23	356
I	52	2.12	35	10.32	386
J	48	4.10	39	20.82	407
Total		295.08		728.22	147

Source: For 1971-73 Hathi Committee, 1980-82 Answers to Parliament questions which appeared in Assochem Bulletin, various issues.

## The Indian Private Sector

It is clearly evident that the MNC's did not contribute on any significant scale to the development of basic drug manufacture. It was the Indian sector that took the challenges of the industry. As observed by the Hathi Committee, and further established by later studies<sup>13</sup> the Indian sector has over a period of time built up its technological capability. As it stands today, except in the case of a few drugs in the category of antibiotics and steroids, the Indian

sector has established its technological competence. In fact, it is reported in a recent study that the Indian sector is capable of producing at least 76.8 per cent of the bulk drugs and 97.5 per cent of the value of formulations.<sup>14</sup> But, the environment since the introduction of the 1978 Drug Policy has been such that it could not make a dent in the industrial output due to the high pressure-selling tactics followed by the MNC's. As the Lev Raj Kumar Committee also observed the MNCs spent several times more on sales promotion than on any genuine R & D.<sup>15</sup>

It is important to mention in this context, certain behavioural characteristics of Indian sector. This sector has a better R & D allocation than the MNCs.<sup>16</sup> It produces more drugs from the basic stage rather than the penultimate stage and over a period of time has developed technologies for 28 new bulk drugs.<sup>17</sup> It also could export and effectively compete in the export market against the MNCs. The point of emphasis is that the internal environment continues to be unfavourable to this sector. Many product areas involving light technology are becoming exclusive preserves of 'Indianised' foreign companies. A warning signal to this effect had already been conveyed by the Hathi Committee when it said that if the foreign companies are left uncontrolled, Indian companies would face the full blast.

### **The failing Public Sector**

In so far as the production of a drug is basically interwoven with that of basic chemicals, it is the public sector enterprise which imparts a fair amount of capability to the industry by downstream manufacture of important antibiotics and synthetic drugs. The Hathi Committee, therefore, assigned a leading role to the public sector. Of the identified<sup>17</sup> essential drugs, the committee recommended the reservation of 34 drugs exclusively for production by the public sector enterprises. But the government diluted this recommendation. It only reserved 25 drugs for the public sector enterprises, 23 for the Indian private sector enterprises and about 69 were open to all sectors. The Hathi Committee wanted at least 60 per cent of the bulk drugs to be formulated by the public sector itself. The record of public sector enterprises with relation to their target is a dismal one. There was a short fall of around 50 per cent in the targeted bulk production by 1982-83. The reasons for the shortfall are complex. The major problem plaguing these enterprises is the failure to upgrade their technology. Instead of a systematic effort to upscale the

technology by investing heavily in R & D through pilot plants and proto-type large scale production as the Hathi Committee had suggested, most of the time they relied on easy options like the import of technology. The experience of HAL with Merck of U.S. is a case in point.<sup>18</sup>

Another major failure arose from the non-implementation of the Hathi Committee recommendation regarding the formulation of the bulk drugs. The formulation activity of the public sector enterprises remains low. Therefore these enterprises have not been able to generate a sufficient surplus for expansion. The failure of the public sector enterprises has provided an alibi for the MNCs to slow down the bulk drug production. But, the fact is that the public sector enterprises have been continuing the role of fuelling the growth of the MNCs and the private sector units by not formulating the bulk drugs they produce. There is credence in the argument that the light technology and high profit areas are thus reserved for other sectors. The involvement of the public sector in high cost areas rendered it unable to generate surplus for further expansion. This has a backlash effect in the form of shortages and cutbacks.

In the discussions on the role of the public sector in pharmaceutical industry, the above aspect is often forgotten. Instead of subsidizing foreign companies, why did not these enterprises go into the formulation area on a large scale? The answer is to be sought in the political economy, for in a developing country like India, the public sector is interconnected with the underlying political process.

### **Technology Development**

The overwhelming emphasis of the Hathi Committee had been on the upgradation of technology through R & D activities. The Committee wanted the proposed National Drug Authority, to plan and supervise the development of indigenous technology and to act as a sole importer of technology in order to ensure the horizontal transfer of technology. The NDA was to be funded with a 2% levy on the sales of all the units of the industry. The Committee also wanted a suitable machinery to be evolved to screen the import of knowhow, to check the type of knowhow imported, the fees paid, the contribution made by foreign technology, and the conditions fulfilled by the foreign companies before payment was made. The first recommendation was incorporated in the new drug policy of 1978 by involving the NCST with public sector research institutions

and national laboratories. A heavy investment of the public sector in R & D was embarked upon. But the other recommendations were however given only a peripheral treatment. There was no check on the payments for the imported technology and remittances on other accounts by foreign firms. On the average, the foreign firms' remittances had been increasing from Rs. 1.98 crores (at current prices) during 1961-74 to Rs. 6.45 crores during 1975-82. As rightly remarked by the Hathi Committee, the drain of foreign exchange by the MNCs has to be viewed in the context of their import bill in relation to their own export of drugs and not in terms of their own sales, inclusive of formulations. When worked out, bearing this in mind, it was found that between 1979-81, 23 foreign companies drained off around Rs. 6,854 lakhs (see Table 7). Another specific recommendation of the Hathi Committee was that those foreign firms whose turnover was in excess of 5 crores per annum should additionally spend at least 5 per cent of their sales turn over on recurring R & D. But by 1982-83, there were 25 firms of foreign origin who had yet to have a registered R & D unit. These companies which have spent more money on R & D, help their parent companies in analysing thousands of chemical compounds, as such expenditure is lower in India than in research centres abroad.<sup>19</sup>

**Table—7**  
Foreign Exchange Drain by MNCs\* in India (Rs. lakhs)

Years	Total inflow (exports and other earnings)	Outflow due to imports	Trade balance	Outflow on account of dividend, royalty, technical fees etc.	Total foreign exchange drain
1	2	3	4	5	6 3 + 5 -2)
1970	2298.05	4533.74	1552.69	762.48	2298.17
1980	2632.28	4290.27	1657.99	748.40	2442.39
1981	2660.01	3939.08	1278.57	834.99	2113.56

\* Relates to only 23 foreign companies

Source: Accochem Parliamentary Digest, dated 9-5-1983

In contrast to the Hathi Committee's verdict on technology development, by giving emphasis to upgradation and rationalisation of available technology, the import of technology was increasingly allowed. It is important to note that following the recommendation of the Hathi Committee, a high dose of foreign technology was injected into the industry by around 45 collaborations between 1976 and 1984. In a single year 1984, 24 collaborations were allowed in the name of modernisation, most of them of repetitive types. It is a matter of concern that we are importing even today technologies for sweeteners, aspirin, adhesive tapes and surgical dressing etc. (See Table 8).

### Price Policy

The committee was of the view that technological dependence can be effectively attacked by a multi-pronged strategy. The major elements of the strategy were (1) a rational price policy which assures that prices are fair to the producer and consumers and (2) the abolition of brandnames. The Hathi Committee which went into pricing recommended that the markup for essential drugs should be reduced and that of non-essential drugs should be given a liberal margin. This recommendation was accepted by the government in a distorted manner, subjecting all bulk drugs to price control instead of a leader price formula as suggested by **the Hathi Committee**. Formulations were grouped into four categories whereas category IV was not subjected to any price control, a separate pricing of each category of production was accepted allowing a markup of 40, 55 and 100 per cent respectively for the other three categories. The rationale of this decision is not clear, for, essential drugs appear in all the three categories. The pharmaceutical industry, crying hoarse over 'unremunerative' margins responded by cutting down the categories of low markup and expanded the decontrolled items.

Table 9 with a sample of 22 firms, indicates the output behaviour of firms in response to price policy. As seen in Table 9, while the products in category I and II are systematically curtailed **those in category IV and decontrolled items increase**. Interestingly enough, the price reduction was easily shifted to non-controlled high margin items. Moreover, regarding the essential categories the Multinationals have successfully challenged the provisions of price controls in the court and systematically lobbied the bureaucrats and decision makers, practically rendering them ineffective. Also, the

prices of imported intermediates and raw materials remained largely outside the price controls. This gave ample scope for the MNCs to resort to transfer pricing and offset the loss, if any, by price controls. We have seen in Table 6 that the incidence of imports has already assumed a higher proportion with the MNCs. The ineffectiveness of price controls is pretty clear from the notice issued by the government recently for the recovery of unintended profits running

**Table—8**  
**Some example of Repetitive Collaboration in Pharmaceutical Industry Approved during 1983-84**

Name of the Drug	Name of the Collaborator
1. Salicylic acid, Salicylated including aspirin	Industrial Export/Import—Romania
2. Sweet 'N' Low (sweetner)	Comberland packing Corpn. U.S.A.
3. Rifampicin	Chong Kum Corporation South Korea
4. Timed release of Pharmaceutical formulation	Sidmak Laboratories India, U.S.A.
5. Adhesive tapes and surgical dressing	S.A. Isoplast, Switzerland
6. Vitamin C	Foster Wheeler, Italy
7. Plaster of Paris bandages	IVF Machine Fabrik, Switzerland

Source: Reply by the Minister of Petroleum & Chemicals (L.S. as Q 6483 (14.5.1983))

**Table—9**  
**Output Behaviour of Firms in Response to Price Policy**

(Amount Rs. lakhs)						
DPCO Category	1978 Amount	Share (%)	1979 Amount	Share (%)	1980 Amount	Share (%)
I	1384	4.5	1477	4.2	1376	3.6
II	5159	16.7	5169	14.8	5041	13.2
III	20720	67.1	23756	67.8	26134	68.6
Decontrolled	3630	11.7	4613	13.2	5547	14.6

Source: NCAER, The Indian Pharmaceutical Industry Problems and Prospects, NCAER, 1984.

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into several crores. An unintended profit is a profit in excess of what the law allows under the Drug Price Control Act 1979.<sup>20</sup> On account of the higher prices charged for an anti-TB drug rifampicin the Government has to recover from the companies around Rs. 3 crores!

This is one side of the picture. On the other hand, there has been a frequent upward revision of drug prices of all the three categories by Government to nullify the effect of cost escalation. For example, the price of Rifampicin, an anti-TB drug was revised six times after 1980. Such examples can be multiplied.<sup>21</sup>

**Table 10-A**

The Percentage increase in the Case of Upward Revision of prices of some basic drugs in response to cost escalation.

Sl. No.	Bulk Drugs	% increase	Sl. No.	Bulk Drugs	% increase
1.	Aspirin	9.30	7.	Chlorophenecol powder	6.93
2.	Bengocaine	31.26	8.	Chloroquin phosphate	7.01
3.	Boric Acid IP Granules	12.81	9.	Doxyegeline	47.25
4.	Boric acid (Powder)	12.47	10.	Procaine HCL	63.70
5.	Boric acid (Crystal)	12.16	11.	Salicyclic acid	59.14
6.	Chlorophenecol Powder	13.67	12.	Menthol	27.18

**Table 10-B**

The percentage increase in the price of formulations in response to cost escalations

Sl. No.	Formulations	% increase	Sl. No.	Formulations	% increase
1.	Aspirin (300) mg. tab	24.94	7.	Thiopentone sid.inj. 0.5 gram acid	30.38
2.	Chloroquin phosphate (mg)	22.76	8.	Thiopentone sod inj. 1.0 gm.	29.48
3.	INH tablets (300 mg)	26.05	9.	Vitamin C Tab 100 mg tab	
4.	Doxyregetine Caps 100 mg, base, cap	34.66	10.	Vitamin C injection	18.68
5.	Kanamycin capsules 250 mg/cap	21.78	11.	Vitamin C. drops 100 mg/ml	19.71
6.	Morphaginanide tablet 500 mg/tab.	19.28			

R.S. Uns. 123 (21.1.85)

Parliamentary Digest No. 2, Jan. 1985

Again, in 1984, the prices of 17 bulk drugs and 47 packs of leader formulations have been increased and those of 9 bulk drugs and 29 packs of leader formulations in 1985. The percentage of increase in the case of upward revision is given in Table 10 A & B.

The uncontrolled category which was meant to compensate for the loss of the controlled category has turned out to be a profit spinner. The extent of price rise in the category of drugs of common use is given in Table 11.

We have tried to show above, that contrary to the complaint of the industry that the controls are insensitive to cost, it has actually been responsive to the cost escalation.

**Table 11**

**Increase in the Prices of Drugs of Common Use**

A Statement showing the prices before Drugs (price control) Order 1979 as well as current price along with percentage of increase is given below.

Sl. No.	Name of the Formulation	Pack size	Price before PCO 1979	Current Price	% increase
(1)	(2)	(3)	(4)	(5)	(6)
1.	<b>PROLUTON DEPOT INJ</b>				
	125 mg/ml	10 Amps	42.00	64.00	54.05
	250 mg/ml	10 Amps	76.00	116.30	53.03
	500 mg/ml	5 amps	70.00	107.25	53.21
2.	<b>TESTOVIRON DEPOT INJ</b>				
	100 mg/ml	10 Amps	51.00	91.00	78.43
	250 mg/ml	10 Amps	95.00	161.90	70.42
3.	<b>ELTROXIN TABS</b>	100s	2.72	5.98	119.85
4.	<b>CALMPOSE, TABS 5 mg</b>	10s	0.93	2.09	124.71
5.	<b>Vicks Cough Drops</b>	2 Dozs	0.25	0.39	56.00
		4 Dozs	0.29	0.89	175.86
		10 Dozs	1.68	2.80	66.60
6.	<b>Halls Lozenges</b>	10s	1.19	2.09	75.63
		250s	30.11	58.28	93.56
7.	<b>Waterbury compound red label</b>	250 ml	5.71		
8.	<b>Panzy Normtabs</b>	100s bottle	38.00	68.00	78.95
9.	<b>Dulcolax Tablets</b>	5 mg.	10.30	14.60	41.75
10.	<b>Algipan Cream</b>	90 grams	5.06	9.31	83.99

Source: Same as 10 A and 10 B

**The Brand name Issue**

One of the major recommendations of the Hathi Committee as a measure to check the high pressure sales techniques and thereby control the price was to abolish brandnames in a phased manner. To begin with the Committee listed 13 drugs whose brandnames should be abolished and should be replaced by generic names. But the new drug policy stipulated the abolition of brandnames of only 5 drugs. The organisations representing the interests of foreign companies opposed the Government policy by a vigorous campaign against distributing medicines by generic names. The argument had been that in Pakistan withdrawing brandnames led to the multiplication of spurious drugs. But the examples of Afghanistan, Bangladesh and advanced countries like the U.S. were deliberately withheld from public knowledge. Meanwhile, four companies (Hoechst, Pfizer, Cyanamid, and Costume Farma) challenged the Government action in the court and the court cancelled the Government decision on brandnames in 1982. Now, brandname in the pharmaceutical industry has become a non issue!

The industry continues to dump spurious and substandard drugs into the market in spite of brandnames continuing to exist (around 25 per cent). Many such drugs belong to foreign companies. One of the major recommendations of the Hathi Committee to check the problem of spurious drugs was to strengthen the existing system of drug inspection in all stages. The cost of this was to be borne by the Central Government. This recommendation, along with several others, to check the existence of spurious drugs, has not been given serious attention. This is clear from the inadequate infrastructure to test medicine. Only nine states have any drug testing laboratories. There are only 600 drug inspectors whereas the workforce needed is around 8000.<sup>22</sup>

**New Drug Policy**

The new drug policy announced on 18th December 1986, after long deliberations and hectic lobbying by the Multinational Corporations had further frustrated the attempt to generate an appropriate product structure at appropriate prices. This is because, instead of seeking a solution to the stagnation of the industry brought about by structural distortions, the new policy had sought a market solution and allowed a price hike to the extent of 25% for essential drugs! Surprisingly, this hike has been permitted without

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undertaking any home work. This testifies the success of lobbying by the MNCs for the relaxation of price controls. Instead of simplifying the procedures and keeping a strict watch on the implementation of price control on essential medicines, the new policy has reduced the existing three categories into two and the number of drugs falling in each category has also been reduced. For example, the first category now consists of only 40 drugs.<sup>23</sup> The mark up has been increased to 75 per cent to 100 per cent in place of the existing 40 and 55 per cent respectively for the first two categories. The number of drugs to be included in the second category are to be announced later after consultation with the industry.

It is a matter of great concern that the New Drug Policy does not appear to have taken seriously the need for a product and price pattern in consonance with social needs. It thereby violates the assurances given regarding the implementation of an integrated health policy which would assure access to essential drugs at reasonable prices.<sup>24</sup> The New Drug Policy had moved towards a market solution by delicensing drug manufacturing and broad banding around 31 drugs. This approach of privatisation of drug production, without doubt, is at the expense of public sector enterprises which have built up large capabilities in the production of basic drugs. Though they have been ailing for years for various reasons, no commitment is made in the new policy to rejuvenate them or to supply them with essential formulations. It appears that public sector enterprises are expected to supply the basic drugs to the formulating Multinational enterprises and remain as their servicing units!

The new policy, while relaxing the price controls, also relieved the Indianised foreign firms of the responsibility of integrating the production of formulations with the manufacture of basic drugs. The Hathi Committee report and subsequently the Drug Policy of 1978 wanted such integration of critical bulk drugs. There was also a kind of reservation of certain other critical drugs for the public sector and the Indian Private Sector. The new policy does not insist on any such integration or reservation. The Hathi Committee and Drug Policy of 1978 insisted on reservation and integration, for, it thought that price control along with the lifting of Trade Marks may induce the foreign firms to conform to the social needs. Now that all these controls have gone, it is likely that foreign firms and 'Indianised' foreign firms will

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consolidate the formulation market with vigorous sales campaigns. Then involvement in the production of basic drugs will perhaps remain minimal.

With regard to the fixing of the bulk/formulation ratio, the new policy has totally abandoned the norms followed in the previous approach based on foreign control. The new policy propose a gradual basis depending upon the turnover.<sup>25</sup> This measure of

treating the Indian firms and "Indianised" foreign firms on an equal footing undermines the very spirit of the policy of protecting the indigenous firms. As the Hathi Committee rightly remarked, "The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places the Indian manufacturers at a disadvantage. On the contrary, if the choice were between a foreign company and an Indian company encouragement should be given to Indian Companies which are technically competent. Somehow or the other there seem to be exaggerated notions about the capabilities of foreign companies vis-a-vis Indian units". The policy which induce unequal competition between the MNCs and Indian firms is likely to put the latter at a disadvantage. The New Drug Policy has also abandoned the question of brand names. It only pays lip service to the problems of quality control and manufacture of hazardous and irrational drugs. We have discussed the magnitude of the problem elsewhere. That new strategy does not realise the seriousness of the issues involved is evident from the fact that such issues are left to be decided by the newly created apex body. Ironically, this 'apex' body will be 'adequately' represented by the industry and since the major interest of the industry is represented by foreign firms, it is anybody's guess what the likely outcome of such a body will be!

### **Need for Multipronged Action**

We have demonstrated above how the recommendations of the Hathi Committee to make the pharmaceutical industry more meaningful in terms of health needs, when embodied in a haphazard manner as in the 1978 Drug Policy, did not lead to the expected results. In fact, the way in which they were implemented gave enough scope to foreign firms to manipulate their sales strategies further sharpening the contradiction between their profit motive and the health needs of the people. To break the stagnation in the industry, the Government announced the New Drug Policy recently and

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resorted to a market solution for the health needs of the people by offering all sorts of incentives to the foreign sector. If history is any guide, such a step is unlikely to deliver the goods.

The importance of the Peoples Science Movement needs hardly any emphasis in this regard. It is encouraging that an organisation like the Kerala Sastra Sahitya Parishad has already taken up the drug issue and has launched a big campaign exposing the anti people exploitative tactics of the MNCs, the question of essential versus non-essential drugs, the rising prices of life saving drugs, the non-implementation of the Hathi Committee recommendations etc. The aim of the campaign is to sensitise the medical profession to these issues and to launch a People's Health Movement for the formulation of a People's Drug Policy with the following major elements: (1) essentiality (2) efficacy (3) safety (4) low cost (5) ease of administration and (6) easy availability. A number of non-governmental organisations in India, interested in drug and related issues have joined together and formed the All India Drug Action Network.<sup>26</sup> All these efforts are significant steps towards arousing consciousness against the prevailing exploitative drug policies in the country.

[This is a slightly revised version of the paper presented at the All India Conference on Pharmaceutical Industry, A decade After Hathi Committee organised by the Kerala Sastra Sahitya Parishad between November 24-25, 1985 at Trivandrum. The author is thankful to K. K. Subramanian, I. S. Gulati and S. J. Patel for comments in revising this in the light of recent drug policy announcement].

### Notes

1. In the context of renewed demand inside and outside the Parliament for more national control of the pharmaceutical industry in the early 70s, the Hathi Committee was appointed in February, 1974. The Committee was asked to outline measures for promoting the growth of the industry with self-reliance in order to make available essential drugs at reasonable prices. See Ministry of Petroleum and Chemicals (1975).
2. For example, in 1981-82, the import percentage of production was 87% for antibiotics, 40% for analgesics, 282% for anti-malarials, 38-33% for antileprotics. See, for details, NCAER (1984).
3. The identification of 'high technology' products is solely on the basis of the answers received to a questionnaire circulated among the MNCs. Some of the elements that make a product high technology are a reaction temperature at above

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250 centigrade, a pressure of ten atmospheres, the number of steps in chemical analysis. These elements are common to most of the products in this industry. If these criteria are applied, almost all the products in this industry may qualify to be in the high technology category.

4. Choudhari S. (1985)

5. See Bidwai P. (1983)

6. Reply to a question to the Minister for Chemicals and Fertilizers (Qn. No. 262 dated 18-3-1985) reproduced in Asschem Parliamentary Digest, August 1985. Interestingly the company in question is going to dilute its equity to 40 percent.

7. See Gopalakrishnan C.V. (1983)

8. They have been registering fresh projects and booked huge additional capacities. Searle India has registered itself for the production of 37 new items in three years. Duphar Interfran for 40 items in just one year, German Remedies for 19 items and Boehringer-Knoll for 24 different drugs, see *India Today*, June 15, 1985.

9. Pillai P.M. (1984)

10. Worked out from the balance sheet of Indianised companies.

11. See, New Drug Policy, *Economic and Political Weekly*, May 27, 1978.

12. UNCTAD, (1979)

13. Choudhari S. (1984).

14. The Report of the Lev Raj Kumar Committee quoted in Mehrotra N.N. (1984).

15. Ibid.

16. Ibid.

17. NCAER (1984).

18. It was found that the type of technology for manufacture of streptomycin that HAI got from Merck was inferior and during the period of collaboration there had been cases of blatant refusal by the collaborator to honour the terms and conditions of collaboration, see for details Gopalakrishnan C.V. (1977).

19. See Man Mohan, (1985).

20. See Collapse of Price Control, *Economic and Political Weekly*, September 8, 1984

21. To quote another example, after a systematic study by the Bureau of Industrial Costs and Prices, the price of Ibuprofen was reduced from Rs 1044.35 per kg to Rs 828.25 on November 1984 and increased to Rs 845.25 on November 5, 1984 and increased to Rs 845.60 on September 25, 1985. The price of the bulk drug metronidazole was also reduced from Rs 497.98 to Rs 363.00 on November 14, 1984 but increased to Rs 450 on September 25, 1985. See *Economic Times*, January 1, 1986.

22. See Drugs, Paper Standards, *Economic and Political Weekly*, March 1984

23. The price control order 1979 covered almost 80% of the drug formulations produced in the category.

24. See The Drug Seventh Five Year Plan, Planning Commission, New Delhi, 1984

25. Upto Rs. 10 crores the ratio will be 1:10, for production in excess of Rs 10 crores and upto Rs 35 crores, the ratio would be 1:7, and production in excess of Rs. 25 crores the ratio would be 1:5.

26. Some of these groups are Voluntary Health Association of India, Medico Friend Circle, Arogya Dakshata Mandal, Delhi Science Forum, Society of Young Scientists, Lok Vignyan Sangathan, etc.

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  5. Man Mohan (1985) "Who Benefits from MNC Drug Firms", *Peace & Solidarity*, November.
  6. Mehrotra, N.M. (1984) "R&D And Technological Development in Indian Industry", paper presented at the Seminar on Indian Pharmaceutical Industry, A Decade After Hathi Committee, between 24-25, November, Trivandrum.
  7. Ministry of Petroleum and Chemicals (1975) *Report of the Committee on Drugs and Pharmaceuticals Industry*, (Chairman Jaisukhlal Hathi), New Delhi.
  8. NCAER (1984) *The Indian Pharmaceutical Industry: Problems and Prospects*, New Delhi.
  9. Pillai P.M. (1984) *The Multinationals and Indian Pharmaceutical Industry*, Kerala Sastra Sahitya Parishad, Trivandrum.
  10. UNCTAD (1979) *Technological Problems in the Indian Pharmaceutical Industry*, Geneva.
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# **R&D and Technological Development in Indian Drug Industry; Policy Perspectives, Problems and Prospects**

**N.N. Mehrotra**

A reasonable growth of Indian Drugs & Pharmaceuticals (D&P) industry has taken place in the post-independence period. While Indian sector has also grown enormously, the companies with significant foreign equity participation continue to influence the Indian scene. The formation of the Hathi Committee in Feb. 1974 to find out "ways and means to meet the growth requirements and broad social objectives before the country", was a significant step towards regulating the D&P industry. Following terms of reference of this committee are to be specially examined in this paper. These pertain to:

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The vies expressed here are those of the author and do not necessarily represent those of the NISTADS or CSIR.

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- (a) To recommend measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research & development.
  - (b) To examine the present arrangements for the flow of technology into the industry, and make recommendations therefor.
  - (c) To recommend measure for effective quality control of drugs, and for rendering assistance to small scale units in this regard, and
  - (d) To recommend measures for providing essential drugs and common household remedies to the general public, especially in the rural areas.<sup>1</sup>

Let us, therefore, examine the developments leading to current situation of technological capabilities and D&P industry. It will be pertinent to analyse the constraints and impact of relevant policy measures on technological self-reliance and production of essential drugs. An attempt will also be made to analyse the existing challenges and develop a picture of the future prospects for the turn of the century.

### **Production Trends**

There has been an almost exponential growth in the production of both the bulk and formulations since the times of the Hathi Committee, or even earlier.<sup>2</sup> However, the contribution of Indian sector towards bulk drug production has steadily increased since 1974 while the share of foreign sector in the bulk drugs production has steadily decreased from 37.8 percent in 1974-75 to a meagre 16.9 percent in 1982-83. The basic observation of Hathi Committee that the foreign sector concentrated towards the production of low-volume, high-cost drugs and formulations with high margins continues to be true even today as shown by an analysis of at least the four therapeutic groups mentioned in Table I. Thus, the drug multinationals (MNCs) in India continue to dominate market share in formulations, without producing enough of bulk drug (Table II). It may be important to mention here that most of these MNCs use large amounts of bulk drugs produced by the same small-scale manufacturers who are used a whipping boys for poor quality control standards. It was reported by Pillai that till 1980-81, the foreign sector had the weakest link for bulk drug production with a ratio of bulk to formulation of 1:12.53 as compared to 1:2.66 for Indian private sector and that of 1:2.26 for the public sector.<sup>3</sup>

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**Table—I**

Sector-wise share in Bulk Drugs and Formulations Production in four Anatomical Groups in 1978

Therapeutic Group	Percent Contribution		
	Foreign	Indian Private	Public
<b>I. Vitamins</b>			
Market Share	79.3	18.6	2.1
Bulk Production	7.2	82.3	10.5
<b>II. Antibiotics</b>			
Market Share	38.4	57.8	3.8
Bulk Production	11.0	49.0	40.0
<b>III. Analgesics</b>			
Market Share	46.3	51.3	2.4
Bulk Production	4.0	72.0	24.0
<b>IV. Anti-Parasitic</b>			
Market Share	67.1	31.5	1.4
Bulk Production	37.0	49.0	14.0

(Bulk Drug Production percentage is approximate since the data for all companies was not available)

Source 1 ORG Retail Store Audit 1978. 2 Government Reports.

**Table—II**

Sector-wise Market Share of the top 30 Companies

Sector	1983		1984		1985	
	No. of companies	Percent share	No. of companies	Percent share	No. of companies	Percent share
Public	1	1.8	1	1.7	1	1.7
Indian	11	24.9	12	24.9	14	26.5
Foreign	18	37.0	17	35.3	15	31.8

Source R G Retail Store Audit of June of these years where market share of the last one year is accounted for.

### Imports and Exports

Another method that these MNCs resort to is through transfer pricing where both the import of bulk drugs as well as intermediates is undertaken at prices much higher to the prevailing international rates<sup>4</sup>. Thus, they drain the country of its foreign exchange, more than what is actually accounted for. This is besides a constant increase in the remittances by companies with foreign equity participation.<sup>5</sup> It is also true that the pricing policies of the government, where more duties are put on intermediates than on bulk drugs themselves, also encourages many companies to import bulk drugs and/or intermediates depending upon the comparative costs of production and import of these items. It is therefore not surprising that a large number of products which are imported in any significant quantities are also produced within the country (Table IIIA & IIIB). In fact, technology has also been imported in the last few years for production of many of these drugs which are imported in large quantities.<sup>6</sup>

**Table—IIIA**

#### Import Pattern of Major Drug Groups

(Rupees in lakhs)

Category/Year		1981-82		1982-83	
		Value of Imports	% of Total major Imports	Value of Imports	% of Total Major Imports
A.	I	100.03	4.87	110.57	3.25
	II	1068.11	27.31	1082.42	31.93
	III	2651.22	67.80	2191.11	64.65
B.	1. Antibiotics	1734.54	44.31	1067.88	35.07
	2. Anti-Malarial	411.56	10.53	535.27	15.43
	3. Anti-TB	245.24	6.27	195.83	5.77
	4. Corticosteroids	159.59	4.07	301.53	5.89
	5. Anti-asthmatics	147.20	3.76	269.46	7.94
	6. Analgesics	161.62	4.13	64.67	1.90
	7. Vitamins	201.93	5.16	268.16	7.90
	8. Cardiovascular	95.18	2.43	55.49	1.63
	9. Sulphas	2.02	0.05	3.96	0.11

Source: Indian Drugs Statistics 1982-83.

**Table—III B**

Annual Imports of more than Rs. one crore

		1981-82				1982-83			
Unit	Quantity % of total	Value % of total	Quantity % of total	Value % of total	Unit	Quantity % of total	Value % of total	Quantity % of total	Value % of total
(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
		Availability	(lakhs)	major imports		Availability	(lakhs)	major imports	
		lity				lity			
		(3)	(4)	(5)		(3)	(4)	(5)	
•Amoxycillin	T	24.73	95	229.03	5.85	21.99	85	186.22	5.49
Oxytetracycline	T	42.3	25	92.30	2.36	42.60	25	116.35	3.43
Griseofulvin	T	15.94	NA	126.52	3.23	15.2	100	122.03	3.60
•Rifampicin	T	16.7	100	663.02	16.95	38.90	100	1205.70	36.06
Vit B2	T	2.7	17	11.03	0.28	18.4	48	63.82	1.88
Vit B6	T	55	100	190.90	4.88	35.00	100	204.34	6.02
Chloroquine	T	166	78	411.56	10.52	213.00	80	523.27	15.43
Decamethassone	T	0.33	78	98.24	2.51	0.259	63	113.93	3.36
•Pyrazinamide	T	20.00	98	113.45	2.90	18.70	100	124.75	3.68
•Prednisolone	T	0.75	35	61.35	1.56	2.30	70	187.60	5.53
•M Dopa	T	19.50	100	95.18	2.43	12.00	80	55.49	1.63
•Cephalexin	T	1.80	—	29.44	0.75	9.63	—	150.17	4.42
•Theophylline	T	113.60	—	99.80	2.68	131.49	—	154.67	4.54
•Ampicillin	T	39.02	—	338.13	8.67	33.06	—	286.95	8.4

Source: Indian Drugs Statistics 1982-83 and Seventh Plan working group on D & P, 1984. GOI.

•Technology also imported recently and imports of many of these have since reduced.

Interestingly enough, exports of bulk drugs have also been increasing besides those of formulations, to both developing and developed countries (Table IV). What is more important is the capability of Indian manufacturers to enter into the market of developed countries for the export of bulk drugs, not only against tropical diseases like metronidazole and Amodiaquin but also for cardiovascular drugs like Nifedipine. It has also been able to export some of the plant based drug intermediates like Beta-Ionone and citric acid etc. All this international competition for exports has been possible despite the fact that raw-material costs for most basic chemicals (including petroleum based ones) continue to be high from international standards. Even then, according to statistics available with the seventh plan working group, Indian prices for several products are internationally competitive<sup>7</sup> (with percent variance up to 200, when it starts to become non-competitive, since the average Indian price also takes care of internal variations. Thus, several manufacturers with better technology/management are able to compete). It is mostly in the case of antibiotics or some newer drugs (eg. not more than 15-20 drugs in anatomical groups of cardiovasculars, analgesic or tranquilizers etc.) that Indian price is significantly higher, with a percent variance of around 300 or more. Even where the cost of bulk drugs is higher in India, the prices of formulations continue to be internationally competitive.

**Table—IV**  
Current Trends in Exports

(Rs. in lakhs)

Items	1982-83	% share	1981-82	% share	1980-81	% share
Finished formulations	5459.6	49.5	4251.4	44.5	4748.6	55.5
Medicinal Castor Oil	4501.3	40.5	4000.7	42.0	2867.1	33.9
Basic Drugs & Phy-to Chemicals	1145.0	9.9	1288.8	13.5	933.9	10.6
Total	11105.9		9540.9		8549.6	

Source: Chemexcil

### **Technological Developments**

How could India reach such a situation without achieving commensurate technological capabilities? Today Indian D&P industry is in a position to indigenously produce some of the latest bulk drugs from almost any therapeutic group that it requires. There are few drugs mainly in the antibiotics and steroids category for which Indian sector lacks reasonably competitive technology. Otherwise, even small-scale sector has technological capabilities to produce a large number of bulk drugs.<sup>8</sup> In fact, there is already enough internal competition even in drugs like sulphamethoxazole and trimethoprim that for these even the international prices had to crash down as a result of technological strengths developed in the small-scale Indian sector.<sup>9</sup> While the foreign sector companies have not really introduced many new drugs in the last several years (MNCs got approval of only 13 out of a total of 49 new drugs cleared by the DCI between 1979 to 1984)<sup>10</sup>, they continue to boast of major technological inputs to seek extraordinary privileges (including expansion and equity non-dilution). Even their claim of bringing in high technology does not stand to logic since Indian sectors have also developed equivalent technological capabilities.<sup>11</sup> In any case the criteria of 'High Technology' were flexible enough to encompass such routine technologies which are used even by a large number of small-scale manufacturers.

A discussion on the technological development in the D&P industry cannot be complete, without proper recognition of the contributions of CSIR labs and those of the public sector undertakings. It has been amply proven that besides the R&D efforts of some private sector companies, both the CSIR labs and the public sector have contributed significantly towards successful development of processes for production of a large number of bulk drugs.<sup>11</sup> While their contributions towards development of new drugs may not be treated as highly satisfactory, even there the output cannot be totally neglected, given the small budgetary inputs (and several other factors).

### **Technology and Patents Act**

It is precisely for these technological capabilities that India has been classified by UNIDO as one of the technologically most advanced countries in the developing world.<sup>12</sup> It may be important to note that production of more than 66 new bulk drugs has been

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initiated in the country since 1972 when the new Patents Act came into operation.<sup>13</sup> Before the introduction of modifications in the Patents Act of 1970, Indian manufacturers were actually stopped from introducing new drugs in the country even when these MNCs would also not be interested to manufacture these in India.<sup>14</sup> While the MNCs would introduce blocking and repetitive patents for all the known and possible processes, the compulsory licencing clause could never be invoked till 1947. Despite a modification in the Patent Act in 1950, only five applications for compulsory licences could be made due to inadequacies in the law and the legal hassles, and out of these such compulsory licences could only be obtained in two cases out of which one was for an MNC subsidiary.<sup>14</sup>

With appropriate modifications in the Patents Act of 1970 (which became operative from 1972), Indian manufacturers could actually produce drugs for which patents were to expire elsewhere in 1980s and 1990s (Table V). It is by now widely accepted that the production technology for a drug requires much more than the patent information and a better route of technology transfer is through foreign collaborations. It may be pertinent to note that during 1979 to 1985, out of the 41 technological collaboration for import of drug production, only two were concerning a MNC subsidiary and the rest were all by Indian companies only.<sup>15</sup>

**Table—V**

An illustrative list of a few bulk drugs for which technology could be indigenously developed or acquired, and production undertaken as a consequence of the Patents Act of 1970.

Period when the Patent Expires/Expired	Name of the drug
1983	Ibuprofen Clofibrate
	Tetramisole & Verapamil
1984	Allopurinol, Betamethasone & Derivatives (1984-87)
1985	Tinidazole, Chromoglycate
1986	Lorazepam
1987	Pyrantel
1988	Propranolol
1989	Mebendazole, Salbutamol, Clotrimazole, Ketoprofen
	Levamisole, Bumetamide
1992	Cimetidine, Metoprolol

While a number of repetitive and blocking patents being filed in India by MNCs may have reduced since 1972, it could not have made much difference on the development of new drugs for the following reasons. Besides the concentration of R&D for development of new drugs in national labs or in the public sector companies, only a few Indian companies or MNCs are involved in this task for the simple logic of inputs. Limited size of the total turnover of most Indian companies is not likely to allow them to generate enough surplus to be ploughed back into basic R&D for development of new drugs. While the nature of research in the national labs and public sector undertakings is not likely to be influenced by any such factors, MNCs are likely to continue their basic R&D for new drug development basically for the benefit of their principals through R&D in India and with all the Indian inputs. Moreover, the continued increase in the R&D expenditure in the D&P industry testifies to the fact that modified patents act had no adverse effect on our R&D efforts.

Table—VI

## R &amp; D Expenditure in the Indian D &amp; P Industry\*

A. Year-wise Year	Expenditure Trend		(Rs. in lakhs)
	R & D Expenditure	Sales Turnover	Percent of STO
75-76	8.00	560	1.4
76-77	10.50	700	1.5
77-78	12.00	900	1.3
78-79	14.75	1050	1.4
79-80	18.00	1150	1.5
80-81	29.30	1465	2.0
82-83	NA	1545	—

\* Total number of companies registered for R & D in 1974 were only 40, while by 1983-84, 78 companies were registered with DST.

## B. Size of Pharmaceutical R &amp; D in 1981-82

Quantum of R & D Expenditure	Number of Companies	Total R & D Expenditure
1. Rs. 1 crores and above	9	16.93
2. Rs. 50 lakhs to 1 crores	6	4.45
3. Rs. 25 lakhs to 50 crores	12	4.43
4. Below Rs 25 lakhs	46	3.49
Total	73	29.3

Source: Department of Science and Technology (DST), GOI

### Research and Development

Despite the fact that Indian companies, with small turnover and market size, can hardly think of competing with the international R&D centres of big MNCs, they have been spending a significant amount of their turnover on R&D (Table VI). As a matter of fact, the D&P industry in India spends about 2% of its turnover on R&D which was the second highest percentage spent in 1980-81 by any industrial sector in the country.<sup>16</sup> While the the R&D expenditure of companies in various sectors has been consistently increasing since 1979-80, there has been some decline in this expenditure by public firms.<sup>17</sup> Interestingly enough, comparison of the R&D expenditure by top 10 Indian and foreign firms clearly indicates that Indian private sector companies are competing well with those in the foreign sector<sup>17</sup>. In effect these companies accounted for most of the R&D expenditure in the private sector.

An analysis of the manpower employed in R&D as well as the nature of R&D of most of Indian companies compares well with foreign subsidiaries, though according to their size. There are hardly 3-4 companies which have any worthwhile programme for development of new drugs. Most other companies, including MNCs restrict their R&D to process development or improvement or towards formulations research.<sup>17</sup>

### Technological Developments and Policy

While there are several factors which have positively helped technological development in the drug industry, the changes in the patents act and the introduction of public sector have had the most significant impacts. Among the factors which have negatively influenced the same, the following three appear to be the most important: (i) the variations in the import policies (both for technology as well as products), (ii) the inability of the government to force companies to produce bulk drugs from basic stage and (iii) inconsistent taxation and pricing policies on both the bulk drugs as well as raw-materials and intermediates. There are large number of cases where indigenous efforts at developing technologies have been badly scuttled because of indiscriminate imports of technologies of those of the drugs themselves. This had been well analysed by a CSIR-JNU joint study for UNCTAD<sup>18</sup> which had also enlisted the ill-effects of the import of foreign technology by the subsidiaries of MNCs themselves also (Table VII).

Table VII

## Technology Imports and MNCs

## A. Analysis of 10 Essential Drugs for Impact of Technology Transfer:

- (i) Foreign Technological imports substituted indigenous efforts, rather than being impetus to Indian Industry.
- (ii) Indigenous technological activity did not get requisite support.
- (iii) Indigenous technology was rather overwhelmed by developed technology which was prepared by market with patents and brand names.
- (iv) Foreign subsidiaries have reluctance in technology transfer for production of basic drugs and rather prefer formulation.

## B. Despite increasing participation of Indian capital, absolute amount of foreign equity participation has increased as a result of:

- (i) Conversion of reserve funds (e.g. dividends)
- (ii) Capitalizations of imported machinery and know-how
- (iii) Purchase of intermediates/raw-materials (transfer pricing)
- (iv) Trade marks/patent user's rights.

Source: Case studies in technology transfer in pharmaceutical industry in India CSIR—JNU study, UNCTAD, 1977.

Table VIII

## R &amp; D or Marketing Preferences:

## I. Comparison of Expenditures on R &amp; D and Marketing by 52 Companies\*

(Rs. in Lakhs)

Expenditure Head	1975-76		1976-77		1978-79	
	Amount	%	Amount	%	Amount	%
A. R & D	107	0.3	136	0.4	156*	0.4
B. Marketing	1317	3.8	1462	3.7	1534	3.6
Ratio of B:A	12		11		10	

\* M. Bhagat, Aspects of Drug Industry in India. Centre for Education and Documentation, Bombay 1982.

## II. MNCs Expenditure on R &amp; D and other Areas\*

Outlays on R & D	Aprox 0.83 %
Outlays on Sales Promotion and Administrative overhead	Approx 33.00 %

\* Lovraj Kumar Committee report, on MNCs which found that this ratio was unduly high in this sector as compared to other industries.

Despite the observations of the Hathi Committee, on which the New Drug Policy (NDP), of 1978 insisted that the MNCs follow a ratio of 1:5 in their bulk to formulation production, this provision has been aptly violated by many companies.<sup>19</sup> In reply to a question raised in the Parliament, it was stated that "in the absence of any provision under the ID&R Act of the 1951 to call back the existing industrial licences and impose fresh conditions thereon, the policy decision contained in para 21 of the NDP can be implemented fully only after the amendment of the said act"<sup>20</sup> Thus, these companies continue to produce these drugs from intermediate and penultimate stages. Similarly, existing customs duties and other taxes levied on many of the intermediates and raw materials used for drug production encourage manufacturers to import these drugs or produce these from penultimate stage. Backward technological integration for production from basic stage is thus relegated to background.

Another aspect of the technological development is horizontal transfer of technology for the production of bulk drugs which has already set in internal competition even in the bulk drugs industry. However, many of these small-scale manufacturers could not have reached to this stage without changes in the Patents Act which were effectively utilized by technocrat entrepreneurs and encouraged from the availability of know-how from national labs and public sector undertakings. However, the share of the formulations production of the indigenous sector (particularly the public sector and the S.S.I. sector) continues to be low and as a result they are unable to compete with the foreign sector companies. This has been made possible because of a large number of factors including the use of brand names and high scale promotion activities of the MNCs. The data presented in Table VII clearly shows that the expenditure by these companies on sales promotion has been 10-12 times more than that on the R&D. Lovraj Kumar Committee also corroborated this fact which found that this ratio was unduly high in this sector as compared to other industries. Lack of appropriate policies have allowed this skewed situation to have reached where the producers of technology intensive bulk drugs have to be content with lesser profits than their formulator counterparts.

This brings in yet another aspect of the drug industry whereby presence of a large number of irrelevant, ineffective and often

## HATHI COMMITTEE

harmful drugs and irrational combinations are also promoted through such trade practices. Thus the drug production pattern in the industry also does not bear any relationship with the real needs of the people.<sup>8</sup> The entire concept of essential drugs pioneered by the Hathi Committee has been neglected, despite the fact that India is a signatory to the WHO's programme on Essential Drugs simply because we have not been able to commit ourselves to this useful concept.

Table IX

Sector-wise Manufacture of Priority Drugs Identified by NDPDC\*

Sector	Number of Drugs manufactured
Indian organized	38
FERA	30
Ex-FERA	16
Public	21
Small-Scale	20

\* A total of 73 drugs are being manufactured in India out of a total of 95 drugs according to the report of the Steering Committee of NDPDC, GOI, 1984.

### Policy Perspectives, Challenges and Prospect

Both R&D as well as technological developments have to be viewed in the context of an appropriate Drug Policy. An appropriate Drug Policy will have to not only consider the development of D&P industry but also ensure its social objectives, namely of providing essential drugs to people at large and at reasonable prices, as envisaged by the Hathi Committee. Accordingly, such a policy will have to ensure development and flow of technology for production of drugs which bear some significant correlation with the needs of our people, reinforcing the concept of essential drugs. This will necessitate identification of lists of essential drugs required at various levels of health care and ensure their production in abundance and at reasonable costs. However, this also cannot be achieved until the freedom to produce a large number of ineffective and harmful drugs and irrational combinations continue, since these can be sold

Table X

Production &amp; Projections for Some Bulk Drugs in four therapeutic groups

Bulk Drug Name	Unit	Lic. Cap	Production			Demand Projections			1999-2000
			1980-81	1981-82	1982-83	1985-86	1988-89	1989-90	
ANTI-TUBE-RCULOSIS									
INH	(I) T	473.6*	179.76	147.7	194.57	350	600	720	0850
PAS and Salts	(I) T	790*	405.46	261.97	288.40	250	250	250	1000
Thiacetazone	(I) T	152.6	34.19	45.52	49.52	60	65	70	0100*
Ethambutol	(III) T	203+	35.6	81.11	121.91	215	370	450	1000
Pyrazinamide	(III) T	NA	150kg	348kg	NA	26.4	35.1	38.7	0050*
Rifampicin	(III) Kg	—		Nil		68.350	133.510	166.890	540.00
ANTI-MALARIAL									
Chloroquin	(II) T	176+	34.72	59.98	82.30	440	590	645	1000
Amodiaquin	(II) T	76	23.15	26.02	30.15	46	70	80	0200*
Auinine & Salts	(II) T	—	15.72	15.11	16.09	20	20	20	—
Primaquine	(I) kg	—		Nil					—
ANTHELMINTIC									
Piperazine & Salts	(II) T	165*	31.87	79.4	136.26	230	270	280	112
Mebendazole	(III) T	33+	4.50	11.03	13.82	43	57	63	32
Tetramisole	(III) T	20	9.33	8.38	6.52	—	—	35	32
Bephenium-Hydroxy Napthoate	(III) T		11.92	10.98	4.15	13	16	17	25*
CARDIO-VASCULAR									
Digoxin	(I) kg	9.8	7.33	2.86	76.23	26	35	39	100*
Di pyridamol	(III) T	—	—	—	—	4.3	6.5	7.4	15*
M-DOPA	T	34	—	0.13	3.37	38	59	68	600

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Glyceryl									
Trinitrate/ (III) T	—	—	—	—	4.6	6.9	8.0	20*	
Isosorbide-									
dinitrate/									
Penta/ery/									
thritol-tetra									
nitrate									
Xanthinol									
Nicotinate (III) T	15.0	10.14	15.40	13.89	16	19	20	30*	
Propranolol									
(III) T	4.95	1.4	4.45	4.12				10*	

Sources: 1. Indian Drugs Statistics 1982-83.

2. Indian Drug Industry 1980-2000 AD, IDMA Report, 1980.

3. Seventh Plan Working Group Report, Ministry of Chemical & Fertilizer.

through high pressure sales promotion tactics, thus increasing the pressure on the meagre per-capita availability of drugs. Of course, steps have to be taken to reduce the costs of these drugs all simultaneously follow a pricing policy which will ensure adequate returns on investments.

Once the concept of Essential Drugs is accepted in principle, it can be mentioned with sufficient confidence that enough technological capabilities exist in the country. This will, however, also require a reorientation of priorities in favour of public sector and restrictions on MNCs to not only further dilute their equities but also to concentrate largely in the areas of bulk essential drugs. Appropriate policy measures can be suggested for the same.

Even if we take a careful look at the list of the 95 priority drugs identified by the NDPDC (one may not, though concur with the list), it is clear that 73 of these are already manufactured in the country (Table IX). Some more are since being produced in the country and the technological capabilities would easily allow us to take care of the rest. Similarly, if we consider the requirements by 2000 AD of drugs in four major therapeutic groups (for example), it is clear that the country either produces most of the essential drugs or has the technological capabilities to produce these (Table X). The problem would essentially remain of slightly higher costs in a few cases which can either be improved through R & D and/or through subsidies rebates on taxes on raw materials and intermediates. However, one need not take a restricted view of the situation. The enormous technological capabilities built in the industry could be

effectively utilized to not only meet the national requirements but also expand into export markets in the Third World countries whose drug requirements are very similar, to that of ours and who largely depend today on MNCs for their requirements.

R&D and technological challenges will, therefore have to be given a different orientation. Furthermore, the R&D incentives to industry will have to be again modified from their present block approach. Thus, more incentives could be given, for example, to the development of technology for production of essential bulk-drugs or developing new drugs in the therapeutic areas identified by appropriate authorities. Differential R&D incentives can be given to industries in different sectors, depending upon their social obligations. Thus, public-sector can be, for example, given more incentives (similar to government sponsored R&D labs) in order to allow them to fulfil their social obligations. It is unfortunate that representatives of various sectors are today unable to see beyond their narrow immediate interests, since the prospects for various sectors can be largely harmonised, if a coherent drug policy is followed.

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# **Drugs Without Multinationals in Indian Drug Industry**

**Sudip Choudhuri**

The drug industry has attracted a lot of attention for quite some time now. Those who have participated in the discussions include a wide range of organisations and individuals, eg. official committees, United Nations units, trade unionists, pharmacologists and doctors, industry associations, academicians, and so on. The literature, however, primarily deals with the activities of the transnational corporations (TNCs). While the critics of the TNCs highlight the nature of the market power possessed by the TNCs (which enables them to charge higher prices, to earn higher profits and to maintain dominant market shares), the sources of such market power (eg. patent system, promotional expenditure), the exaggerated claims made by the TNCs about the therapeutic value of the drugs developed by them, the over-pricing by the TNCs of the materials imported into the developing countries etc, the defenders of the present structure dominated by the TNCs try to counter these arguments. The question of manufacturing technology developed by indigenous firms in the developing countries has been neglected in the literature, although it has a bearing on the debate regarding the role of the TNCs in the developing countries. By indigenous firms we mean firms which are controlled not by the TNCs, but independent of them by those belonging to the developing countries themselves.

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The development of new drugs is one of the most significant features of the modern drug industry. Various questions have been raised against the R&D activities of the TNCs. But in contrast to the TNCs, the indigenous firms in the developing countries hardly participate in any research for new drugs. In India, eg. the indigenous private sector has not yet developed any new drug, ie, a new chemical entity, the public sector has done only one, viz. Hamycin. A few other new drugs have been developed due to indigenous efforts at university, government research laboratories etc. (It may, however, be noted that scientist from the developing countries did contribute to the development of new drugs in TNC laboratories.) It is possible that the poor performance of the indigenous firms regarding development of new drugs has obscured the proper appreciation of the role they otherwise are capable of playing. Research for developing new drugs is basically different from research for developing technologies for manufacturing existing drugs. The relative absence of the former in the developing countries does not imply that manufacturing technologies also cannot be or have not been developed through indigenous efforts. It does not follow that TNCs are indispensable for manufacturing drugs in the developing countries to satisfy the health needs of the people. Ramachandran and Rangarao, in fact, note that Soviet Union and Japan have developed their drug industry without the participation of foreigners though they have made insignificant contribution to the development of new drugs. The dominance of the TNCs, accounting for the low market share of the indigenous firms, does not necessarily imply that the latter are incapable of producing more. It is possible that the indigenous firms have the manufacturing technology but because of competition from TNCs in the market or other constraints, they do not manufacture many drugs or do so in smaller quantities.

Our study mainly deals with the question of development of manufacturing technologies by the indigenous firms in the context of manufacturing activities of the TNCs in India. The basic objective of this paper is to analysis whether, and if so, to what extent, manufacturing technology is available with the indigenous sector (IS) to replace drug manufacturing by the TNCs in India. The latter refers to those firms in India which are solely controlled by the TNCs from the developed countries. The IS consists of the indigenous

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firms, ie, those solely controlled by Indians.

In Section I, we will discuss the nature of the sample of drug firms used for this study. The technology of drug manufacturer has basically two components: (a) bulk drugs production, ie, the production of the active ingredient present in the drugs and (b) formulation production, ie, the processing of bulk drugs into finished dosage forms such as tablets, capsules, ointments etc. In Section II, we will first identify the bulk drugs manufactured by the TNCs during 1976/76-77 (ie. 1976 or 1976/77) and 1977/77-78. Then we will discuss the criteria and provide estimates of the proportion of the value of bulk drug production of the TNCs, which the IS can replace. We will also examine whether the bulk drugs for which technology is not available with the IS involve manufacturing processes more complex than those for which technology is available. In Section III after analysing the sectoral market shares of formulation sales, we will similarly discuss the extent to which the IS has the technology to replace the production and sale of formulations by the TNCs.

In the context of our discussion of the possible replacement of the manufacturing activities of the TNCs by the IS, it is relevant to examine whether the drugs produced by the latter induce the intended therapeutic effect or at least the same effect as claimed for the drugs sold by the TNCs. In Section IV and V we will deal with the related issues of quality and bio-availability respectively. It may also be argued in this context that to replace the TNCs, the IS must have not only the capability to produce, but also to do so efficiently. In Section VI, we will compare the costs of production of the IS and the TNCs, to see whether the latter is economically more efficient. We have, however, cost data for only six bulk drugs. But TNCs in general are known to over-price their imports of raw materials which raises the cost of production. For the remaining bulk drugs and formulations, even if we assume that the TNCs are more efficient in terms of the other components of costs, the total cost of production may not be lower, depending on the extent of over-pricing. In Section VII, we will provide some estimates of over-pricing by the TNCs in India. If the IS manufactures and sells drugs at prices lower than those of the TNCs, as some studies on drug prices in India indicate, then it becomes difficult to question, on grounds of efficiency, the replacement of the TNCs by the IS. Assuming that the TNCs are

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technology by investing heavily in R & D through pilot plants and proto-type large scale production as the Hathi Committee had suggested, most of the time they relied on easy options like the import of technology. The experience of HAL with Merck of U.S. is a case in point<sup>18</sup>

Another major failure arose from the non-implementation of the Hathi Committee recommendation regarding the formulation of the bulk drugs. The formulation activity of the public sector enterprises remains low. Therefore these enterprises have not been able to generate a sufficient surplus for expansion. The failure of the public sector enterprises has provided an alibi for the MNCs to **slow** down the bulk drug production. But, the fact is that the public sector enterprises have been continuing the role of fuelling the growth of the MNCs and the private sector units by not formulating the bulk drugs they produce. There is credence in the argument that the light technology and high profit areas are thus reserved for other sectors. The involvement of the public sector in high cost areas rendered it unable to generate surplus for further expansion. This has a backlash effect in the form of shortages and cutbacks.

In the discussions on the role of the public sector in pharmaceutical industry, the above aspect is often forgotten. Instead of subsidizing foreign companies, why did not these enterprises go into the formulation area on a large scale? The answer is to be sought in the political economy, for in a developing country like India, the public sector is interconnected with the underlying political process.

### **Technology Development**

The overwhelming emphasis of the Hathi Committee had been on the upgradation of technology through R & D activities. The Committee wanted the proposed National Drug Authority, to plan and supervise the development of indigenous technology and to act as a sole importer of technology in order to ensure the horizontal transfer of technology. The NDA was to be funded with a 2% levy on the sales of all the units of the industry. The Committee also wanted a suitable machinery to be evolved to screen the import of knowhow, to check the type of knowhow imported, the fees paid, the contribution made by foreign technology, and the conditions fulfilled by the foreign companies before payment was made. The first recommendation was incorporated in the new drug policy of 1978 by involving the NCST with public sector research institutions

and national laboratories. A heavy investment of the public sector in R & D was embarked upon. But the other recommendations were however given only a peripheral treatment. There was no check on the payments for the imported technology and remittances on other accounts by foreign firms. On the average, the foreign firms' remittances had been increasing from Rs. 1.98 crores (at current prices) during 1961-74 to Rs. 6.45 crores during 1975-82. As rightly remarked by the Hathi Committee, the drain of foreign exchange by the MNCs has to be viewed in the context of their import bill in relation to their own export of drugs and not in terms of their own sales, inclusive of formulations. When worked out, bearing this in mind, it was found that between 1979-81, 23 foreign companies drained off around Rs. 6,854 lakhs (see Table 7). Another specific recommendation of the Hathi Committee was that those foreign firms whose turnover was in excess of 5 crores per annum should additionally spend at least 5 per cent of their sales turn over on recurring R & D. But by 1982-83, there were 25 firms of foreign origin who had yet to have a registered R & D unit. These companies which have spent more money on R & D, help their parent companies in analysing thousands of chemical compounds, as such expenditure is lower in India than in research centres abroad.<sup>19</sup>

Table—7

Foreign Exchange Drain by MNCs\* in India (Rs. lakhs)

Years	Total inflow (exports and other earnings)	Outflow due to imports	Trade balance	Outflow on account of dividend, royalty, technical fees etc.	Total foreign exchange drain
1	2	3	4	5	6 3 + 5 -2)
1970	2298.05	4533.74	1552.69	762.48	2298.17
1980	2632.28	4290.27	1657.99	748.40	2442.39
1981	2660.01	3939.08	1278.57	834.99	2113.56

\* Relates to only 23 foreign companies

Source: Accochem Parliamentary Digest, dated 9-5-1983.

In contrast to the Hathi Committee's verdict on technology development, by giving emphasis to upgradation and rationalisation of available technology, the import of technology was increasingly allowed. It is important to note that following the recommendation of the Hathi Committee, a high dose of foreign technology was injected into the industry by around 45 collaborations between 1976 and 1984. In a single year 1984, 24 collaborations were allowed in the name of modernisation, most of them of repetitive types. It is a matter of concern that we are importing even today technologies for sweetners, aspirin, adhesive tapes and surgical dressing etc. (See Table 8).

### Price Policy

The committee was of the view that technological dependence can be effectively attacked by a multi-pronged strategy. The major elements of the strategy were (1) a rational price policy which assures that prices are fair to the producer and consumers and (2) the abolition of brandnames. The Hathi Committee which went into pricing recommended that the markup for essential drugs should be reduced and that of non-essential drugs should be given a liberal margin. This recommendation was accepted by the government in a distorted manner, subjecting all bulk drugs to price control instead of a leader price formula as suggested by **the Hathi Committee**. Formulations were grouped into four categories whereas category IV was not subjected to any price control, a separate pricing of each category of production was accepted allowing a markup of 40, 55 and 100 per cent respectively for the other three categories. The rationale of this decision is not clear, for, essential drugs appear in all the three categories. The pharmaceutical industry, crying hoarse over 'unremunerative' margins responded by cutting down the categories of low markup and expanded the decontrolled items.

Table 9 with a sample of 22 firms, indicates the output behaviour of firms in response to price policy. As seen in Table 9, while the products in category I and II are systematically curtailed **those in category IV and decontrolled items increase**. Interestingly enough, the price reduction was easily shifted to non-controlled high margin items. Moreover, regarding the essential categories the Multinationals have successfully challenged the provisions of price controls in the court and systematically lobbied the bureaucrats and decision makers, practically rendering them ineffective. Also, the

prices of imported intermediates and raw materials remained largely outside the price controls. This gave ample scope for the MNCs to resort to transfer pricing and offset the loss, if any, by price controls. We have seen in Table 6 that the incidence of imports has already assumed a higher proportion with the MNCs. The ineffectiveness of price controls is pretty clear from the notice issued by the government recently for the recovery of unintended profits running

**Table—8**  
**Some example of Repetitive Collaboration in Pharmaceutical Industry Approved during 1983-84**

Name of the Drug	Name of the Collaborator
1. Salicylic acid, Salicylated including aspirin	Industrial Export Import—Romania
2. Sweet 'N' Low (sweetner)	Comberland packing Corpn. U.S.A
3. Rifampicin	Chong Kum Corporation South Korea
4. Timed release of Pharmaceutical formulation	Sidmak Laboratories India, U.S.A.
5. Adhesive tapes and surgical dressing	S.A. Isoplast, Switzerland
6. Vitamin C	Foster Wheeler, Italy
7. Plaster of Paris bandages	IVE Machine Fabrik, Switzerland

Source: Reply by the Minister of Petroleum & Chemicals (L.S.) as Q. 6483 (14.8.1983)

**Table—9**  
**Output Behaviour of Firms in Response to Price Policy**

DPCO Category	1978		1979		1980	
	Amount	Share (%)	Amount	Share (%)	Amount	Share (%)
I	1384	4.5	1477	4.2	1376	3.6
II	5159	16.7	5169	14.8	5041	13.2
III	20720	67.1	23756	67.8	26134	68.6
Decontrolled	3630	11.7	4613	13.2	5547	14.6

Source: NCAER, The Indian Pharmaceutical Industry: Problems and Prospects, NCAER, 1984.

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into several crores. An unintended profit is a profit in excess of what the law allows under the Drug Price Control Act 1979.<sup>20</sup> On account of the higher prices charged for an anti-TB drug rifampicin the Government has to recover from the companies around Rs. 3 crores!

This is one side of the picture. On the other hand, there has been a frequent upward revision of drug prices of all the three categories by Government to nullify the effect of cost escalation. For example, the price of Rifampicin, an anti-TB drug was revised six times after 1980. Such examples can be multiplied.<sup>21</sup>

**Table 10-A**

The Percentage increase in the Case of Upward Revision of prices of some basic drugs in response to cost escalation.

Sl. No.	Bulk Drugs	% increase	Sl. No.	Bulk Drugs	% increase
1.	Aspirin	9.30	7.	Chlorophenecol powder	6.93
2.	Bengocaine	31.26	8.	Chloroquin phosphate	7.01
3.	Boric Acid IP Granules	12.81	9.	Doxyegeline	47.25
4.	Boric acid (Powder)	12.47	10.	Procaine HCL	63.70
5.	Boric acid (Crystal)	12.16	11.	Salicycye acid	59.14
6.	Chlorophenecol Powder	13.67	12.	Menthol	27.18

**Table 10-B**

The percentage increase in the price of formulations in response to cost escalations

Sl. No.	Formulations	% increase	Sl. No.	Formulations	% increase
1.	Aspirin (300) mg tab	24.94	7.	Thiopentone sid inj. 0.5 gram acid	30.38
2.	Chloroquin phosphate (mg)	22.76	8.	Thiopentone sod inj. 1.0 gm	29.48
3.	INH tablets (300 mg)	26.05	9.	Vitamin C Tab 100 mg tab	
4.	Doxyregetine Caps 100 mg/ base/cap	34.66	10.	Vitamin C injection	18.68
5.	Kanamycin capsules 250 mg/cap	21.78	11.	Vitamin C. drops 100 mg/ml	19.71
6.	Morphaginanide tablet 500 mg/tab.	19.28			

R.S. Uns. 123 (21.1.85)

Parliamentary Digest No. 2, Jan. 1985

Again, in 1984, the prices of 17 bulk drugs and 47 packs of leader formulations have been increased and those of 9 bulk drugs and 29 packs of leader formulations in 1985. The percentage of increase in the case of upward revision is given in Table 10 A & B.

The uncontrolled category which was meant to compensate for the loss of the controlled category has turned out to be a profit spinner. The extent of price rise in the category of drugs of common use is given in Table 11.

We have tried to show above, that contrary to the complaint of the industry that the controls are insensitive to cost, it has actually been responsive to the cost escalation.

**Table 11**

**Increase in the Prices of Drugs of Common Use**

A Statement showing the prices before Drugs (price control) Order 1979 as well as current price along with percentage of increase is given below

Sl. No.	Name of the Formulation	Pack size	Price before PCO 1979	Current Price	% increase
(1)	(2)	(3)	(4)	(5)	(6)
1.	<b>PROLUTON DEPOT INJ</b>				
	125 mg/ml	10 Amps	42.00	64.00	54.05
	250 mg/ml	10 Amps	76.00	116.30	53.03
	500 mg/ml	5 amps	70.00	107.25	53.21
2.	<b>TESTOVIRON DEPOT INJ</b>				
	100 mg/ml	10 Amps	51.00	91.00	78.43
	250 mg/ml	10 Amps	95.00	161.90	70.42
3.	ELTROXIN TABS	100s	2.72	5.98	119.85
4.	CALMPOSE, TABS 5 mg	10s	0.93	2.09	124.71
5.	Vicks Cough Drops	2 Dozs	0.25	0.39	56.00
		4 Dozs	0.29	0.89	175.86
		10 Dozs	1.68	2.80	66.60
6.	Halls Lozenges	10s	1.19	2.09	75.63
		250s	30.11	58.28	93.56
7.	Waterbury compound red label	250 ml	5.71		
8.	Panzy Normtabs	100s bottle	38.00	68.00	78.95
9.	Dulcolax Tablets	5 mg.	10.30	14.60	41.75
10.	Algipan Cream	90 grams	5.06	9.31	83.99

Source: Same as 10 A and 10 B

**The Brand name Issue**

One of the major recommendations of the Hathi Committee as a measure to check the high pressure sales techniques and thereby control the price was to abolish brandnames in a phased manner. To begin with the Committee listed 13 drugs whose brandnames should be abolished and should be replaced by generic names. But the new drug policy stipulated the abolition of brandnames of only 5 drugs. The organisations representing the interests of foreign companies opposed the Government policy by a vigorous campaign against distributing medicines by generic names. The argument had been that in Pakistan withdrawing brandnames led to the multiplication of spurious drugs. But the examples of Afghanistan, Bangladesh and advanced countries like the U.S. were deliberately withheld from public knowledge. Meanwhile, four companies (Hoechst, Pfizer, Cyanamid, and Costume Farma) challenged the Government action in the court and the court cancelled the Government decision on brandnames in 1982. Now, brandname in the pharmaceutical industry has become a non issue!

The industry continues to dump spurious and substandard drugs into the market in spite of brandnames continuing to exist (around 25 per cent). Many such drugs belong to foreign companies. One of the major recommendations of the Hathi Committee to check the problem of spurious drugs was to strengthen the existing system of drug inspection in all stages. The cost of this was to be borne by the Central Government. This recommendation, along with several others, to check the existence of spurious drugs, has not been given serious attention. This is clear from the inadequate infrastructure to test medicine. Only nine states have any drug testing laboratories. There are only 600 drug inspectors whereas the workforce needed is around 8000.<sup>22</sup>

**New Drug Policy**

The new drug policy announced on 18th December 1986, after long deliberations and hectic lobbying by the Multinational Corporations had further frustrated the attempt to generate an appropriate product structure at appropriate prices. This is because, instead of seeking a solution to the stagnation of the industry brought about by structural distortions, the new policy had sought a market solution and allowed a price hike to the extent of 25% for essential drugs! Surprisingly, this hike has been permitted without

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undertaking any home work. This testifies the success of lobbying by the MNCs for the relaxation of price controls. Instead of simplifying the procedures and keeping a strict watch on the implementation of price control on essential medicines, the new policy has reduced the existing three categories into two and the number of drugs falling in each category has also been reduced. For example, the first category now consists of only 40 drugs.<sup>23</sup> The mark up has been increased to 75 per cent to 100 per cent in place of the existing 40 and 55 per cent respectively for the first two categories. The number of drugs to be included in the second category are to be announced later after consultation with the industry.

It is a matter of great concern that the New Drug Policy does not appear to have taken seriously the need for a product and price pattern in consonance with social needs. It thereby violates the assurances given regarding the implementation of an integrated health policy which would assure access to essential drugs at reasonable prices.<sup>24</sup> The New Drug Policy had moved towards a market solution by delicensing drug manufacturing and broad banding around 31 drugs. This approach of privatisation of drug production, without doubt, is at the expense of public sector enterprises which have built up large capabilities in the production of basic drugs. Though they have been ailing for years for various reasons, no commitment is made in the new policy to rejuvenate them or to supply them with essential formulations. It appears that public sector enterprises are expected to supply the basic drugs to the formulating Multinational enterprises and remain as their servicing units!

The new policy, while relaxing the price controls, also relieved the Indianised foreign firms of the responsibility of integrating the production of formulations with the manufacture of basic drugs. The Hathi Committee report and subsequently the Drug Policy of 1978 wanted such integration of critical bulk drugs. There was also a kind of reservation of certain other critical drugs for the public sector and the Indian Private Sector. The new policy does not insist on any such integration or reservation. The Hathi Committee and Drug Policy of 1978 insisted on reservation and integration, for, it thought that price control along with the lifting of Trade Marks may induce the foreign firms to conform to the social needs. Now that all these controls have gone, it is likely that foreign firms and 'Indianised' foreign firms will

consolidate the formulation market with vigorous sales campaigns. Then involvement in the production of basic drugs will perhaps remain minimal.

With regard to the fixing of the bulk/formulation ratio, the new policy has totally abandoned the norms followed in the previous approach based on foreign control. The new policy propose a gradual basis depending upon the turnover.<sup>25</sup> This measure of

treating the Indian firms and "Indianised" foreign firms on an equal footing undermines the very spirit of the policy of protecting the indigenous firms. As the Hathi Committee rightly remarked, "The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places the Indian manufacturers at a disadvantage. On the contrary, if the choice were between a foreign company and an Indian company encouragement should be given to Indian Companies which are technically competent. Somehow or the other there seem to be exaggerated notions about the capabilities of foreign companies vis-a-vis Indian units". The policy which induce unequal competition between the MNCs and Indian firms is likely to put the latter at a disadvantage. The New Drug Policy has also abandoned the question of brand names. It only pays lip service to the problems of quality control and manufacture of hazardous and irrational drugs. We have discussed the magnitude of the problem elsewhere. That new strategy does not realise the seriousness of the issues involved is evident from the fact that such issues are left to be decided by the newly created apex body. Ironically, this 'apex' body will be 'adequately' represented by the industry and since the major interest of the industry is represented by foreign firms, it is anybody's guess what the likely outcome of such a body will be!

### **Need for Multipronged Action**

We have demonstrated above how the recommendations of the Hathi Committee to make the pharmaceutical industry more meaningful in terms of health needs, when embodied in a haphazard manner as in the 1978 Drug Policy, did not lead to the expected results. In fact, the way in which they were implemented gave enough scope to foreign firms to manipulate their sales strategies further sharpening the contradiction between their profit motive and the health needs of the people. To break the stagnation in the industry, the Government announced the New Drug Policy recently and

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resorted to a market solution for the health needs of the people by offering all sorts of incentives to the foreign sector. If history is any guide, such a step is unlikely to deliver the goods.

The importance of the Peoples Science Movement needs hardly any emphasis in this regard. It is encouraging that an organisation like the Kerala Sastra Sahitya Parishad has already taken up the drug issue and has launched a big campaign exposing the anti people exploitative tactics of the MNCs, the question of essential versus non-essential drugs, the rising prices of life saving drugs, the non-implementation of the Hathi Committee recommendations etc. The aim of the campaign is to sensitise the medical profession to these issues and to launch a People's Health Movement for the formulation of a People's Drug Policy with the following major elements: (1) essentiality (2) efficacy (3) safety (4) low cost (5) ease of administration and (6) easy availability. A number of non-governmental organisations in India, interested in drug and related issues have joined together and formed the All India Drug Action Network.<sup>26</sup> All these efforts are significant steps towards arousing consciousness against the prevailing exploitative drug policies in the country.

[This is a slightly revised version of the paper presented at the All India Conference on Pharmaceutical Industry: A decade After Hathi Committee organised by the Kerala Sastra Sahitya Parishad between November 24-25, 1985 at Trivandrum. The author is thankful to K. K. Subramanian, I. S. Gulati and S. J. Patel for comments in revising this in the light of recent drug policy announcement].

### Notes

1. In the context of renewed demand inside and outside the Parliament for more national control of the pharmaceutical industry in the early 70s, the Hathi Committee was appointed in February 1974. The Committee was asked to outline measures for promoting the growth of the industry with self-reliance in order to make available essential drugs at reasonable prices. See Ministry of Petroleum and Chemicals (1975).
2. For example, in 1981-82 the import percentage of production was 87% for antibiotics, 40% for analgesics, 282% for anti-malarials, 38-33% for antileptics. See, for details, NCAER (1984).
3. The identification of 'high technology' products is solely on the basis of the answers received to a questionnaire circulated among the MNCs. Some of the elements that make a product high technology are a reaction temperature at above

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250 centigrade, a pressure of ten atmospheres, the number of steps in chemical analysis. These elements are common to most of the products in this industry. If these criteria are applied, almost all the products in this industry may qualify to be in the high technology category.

4. Choudhari S. (1985)

5. See Bidwai P. (1983)

6. Reply to a question to the Minister for Chemicals and Fertilizers (Qn. No. 262 dated 18-3-1985) reproduced in Asschem Parliamentary Digest, August 1985. Interestingly the company in question is going to dilute its equity to 40 percent.

7. See Gopalakrishnan C.V. (1983)

8. They have been registering fresh projects and booked huge additional capacities. Searle India has registered itself for the production of 37 new items in three years. Duphar Interfran for 40 items in just one year, German Remedies for 19 items and Boehringer-Knoll for 24 different drugs, see *India Today*, June 15, 1985.

9. Pillai P.M. (1984)

10. Worked out from the balance sheet of Indianised companies.

11. See, New Drug Policy, *Economic and Political Weekly*, May 27, 1978.

12. UNCTAD, (1979)

13. Choudhari S. (1984).

14. The Report of the Lev Raj Kumar Committee quoted in Mehrotra N.N. (1984).

15. Ibid.

16. Ibid.

17. NCAER (1984).

18. It was found that the type of technology for manufacture of streptomycin that HAI got from Merck was inferior and during the period of collaboration there had been cases of blatant refusal by the collaborator to honour the terms and conditions of collaboration, see for details Gopalakrishnan C.V. (1977).

19. See Man Mohan, (1985).

20. See Collapse of Price Control, *Economic and Political Weekly*, September 8, 1984

21. To quote another example, after a systematic study by the Bureau of Industrial Costs and Prices, the price of Ibuprofen was reduced from Rs 1044.35 per kg. to Rs 828.25 on November 1984 and increased to Rs 845.25 on November 5, 1984 and increased to Rs 845.60 on September 25, 1985. The price of the bulk drug metronidazole was also reduced from Rs 497.98 to Rs 363.00 on November 14, 1984 but increased to Rs 450 on September 25, 1985. See *Economic Times*, January 1, 1986.

22. See Drugs, Paper Standards, *Economic and Political Weekly*, March 1984

23. The price control order 1979 covered almost 80% of the drug formulations produced in the category.

24. See, The Drug Seventh Five Year Plan, Planning Commission, New Delhi, 1984

25. Upto Rs 10 crores the ratio will be 1:10, for production in excess of Rs 10 crores and upto Rs 35 crores, the ratio would be 1:7, and production in excess of Rs 25 crores the ratio would be 1:5.

26. Some of these groups are Voluntary Health Association of India, Medico Friend Circle, Arogya Dakshata Mandal, Delhi Science Forum, Society of Young Scientists, Lok Vignyan Sangathan, etc.

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  5. Man Mohan (1985) "Who Benefits from MNC Drug Firms", *Peace & Solidarity*, November.
  6. Mehrotra, N.M. (1984) "R&D And Technological Development in Indian Industry", paper presented at the Seminar on Indian Pharmaceutical Industry, A Decade After Hathi Committee, between 24-25, November, Trivandrum.
  7. Ministry of Petroleum and Chemicals (1975) *Report of the Committee on Drugs and Pharmaceuticals Industry*, (Chairman Jaisukhlal Hathi), New Delhi.
  8. NCAER (1984) *The Indian Pharmaceutical Industry: Problems and Prospects*, New Delhi.
  9. Pillai P.M. (1984) *The Multinationals and Indian Pharmaceutical Industry* Kerala Sastra Sahitya Parishad, Trivandrum.
  10. UNCTAD (1979) *Technological Problems in the Indian Pharmaceutical Industry*, Geneva.
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# **R&D and Technological Development in Indian Drug Industry; Policy Perspectives, Problems and Prospects**

**N.N. Mehrotra**

A reasonable growth of Indian Drugs & Pharmaceuticals (D&P) industry has taken place in the post-independence period. While Indian sector has also grown enormously, the companies with significant foreign equity participation continue to influence the Indian scene. The formation of the Hathi Committee in Feb. 1974 to find out "ways and means to meet the growth requirements and broad social objectives before the country", was a significant step towards regulating the D&P industry. Following terms of reference of this committee are to be specially examined in this paper. These pertain to:

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The vies expressed here are those of the author and do not necessarily represent those of the NISTADS or CSIR.

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- (a) To recommend measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research & development.
  - (b) To examine the present arrangements for the flow of technology into the industry, and make recommendations therefor.
  - (c) To recommend measure for effective quality control of drugs, and for rendering assistance to small scale units in this regard, and
  - (d) To recommend measures for providing essential drugs and common household remedies to the general public, especially in the rural areas.<sup>1</sup>

Let us, therefore, examine the developments leading to current situation of technological capabilities and D&P industry. It will be pertinent to analyse the constraints and impact of relevant policy measures on technological self-reliance and production of essential drugs. An attempt will also be made to analyse the existing challenges and develop a picture of the future prospects for the turn of the century.

### Production Trends

There has been an almost exponential growth in the production of both the bulk and formulations since the times of the Hathi Committee, or even earlier.<sup>2</sup> However, the contribution of Indian sector towards bulk drug production has steadily increased since 1974 while the share of foreign sector in the bulk drugs production has steadily decreased from 37.8 percent in 1974-75 to a meagre 16.9 percent in 1982-83. The basic observation of Hathi Committee that the foreign sector concentrated towards the production of low-volume, high-cost drugs and formulations with high margins continues to be true even today as shown by an analysis of at least the four therapeutic groups mentioned in Table I. Thus, the drug multinationals (MNCs) in India continue to dominate market share in formulations, without producing enough of bulk drug (Table II). It may be important to mention here that most of these MNCs use large amounts of bulk drugs produced by the same small-scale manufacturers who are used a whipping boys for poor quality control standards. It was reported by Pillai that till 1980-81, the foreign sector had the weakest link for bulk drug production with a ratio of bulk to formulation of 1:12.53 as compared to 1:2.66 for Indian private sector and that of 1:2.26 for the public sector.<sup>3</sup>

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**Table—I**

Sector-wise share in Bulk Drugs and Formulations Production in four Anatomical Groups in 1978

Therapeutic Group	Percent Contribution		
	Foreign	Indian Private	Public
<b>I. Vitamins</b>			
Market Share	79.3	18.6	2.1
Bulk Production	7.2	82.3	10.5
<b>II. Antibiotics</b>			
Market Share	38.4	57.8	3.8
Bulk Production	11.0	49.0	40.0
<b>III. Analgesics</b>			
Market Share	46.3	51.3	2.4
Bulk Production	4.0	72.0	24.0
<b>IV. Anti-Parasitic</b>			
Market Share	67.1	31.5	1.4
Bulk Production	37.0	49.0	14.0

(Bulk Drug Production percentage is approximate since the data for all companies was not available)

Source: 1. ORG Retail Store Audit 1978. 2. Government Reports.

**Table—II**

Sector-wise Market Share of the top 30 Companies

Sector	1983		1984		1985	
	No. of companies	Percent share	No. of companies	Percent share	No. of companies	Percent share
Public	1	1.8	1	1.7	1	1.7
Indian	11	24.9	12	24.9	14	26.5
Foreign	18	37.0	17	35.3	15	31.8

Source: R. G. Retail Store Audit of June of these years where market share of the last one year is accounted for.

### Imports and Exports

Another method that these MNCs resort to is through transfer pricing where both the import of bulk drugs as well as intermediates is undertaken at prices much higher to the prevailing international rates<sup>4</sup>. Thus, they drain the country of its foreign exchange, more than what is actually accounted for. This is besides a constant increase in the remittances by companies with foreign equity participation.<sup>5</sup> It is also true that the pricing policies of the government, where more duties are put on intermediates than on bulk drugs themselves, also encourages many companies to import bulk drugs and/or intermediates depending upon the comparative costs of production and import of these items. It is therefore not surprising that a large number of products which are imported in any significant quantities are also produced within the country (Table IIIA & IIIB). In fact, technology has also been imported in the last few years for production of many of these drugs which are imported in large quantities.<sup>6</sup>

**Table—IIIA**

#### Import Pattern of Major Drug Groups

(Rupees in lakhs)

Category/Year		1981-82		1982-83	
		Value of Imports	% of Total major Imports	Value of Imports	% of Total Major Imports
A.	I	100.03	4.87	110.57	3.25
	II	1068.11	27.31	1082.42	31.93
	III	2651.22	67.80	2191.11	64.65
B.	1. Antibiotics	1734.54	44.31	1067.88	35.07
	2. Anti-Malarial	411.56	10.53	535.27	15.43
	3. Anti-TB	245.24	6.27	195.83	5.77
	4. Corticosteroids	159.59	4.07	301.53	5.89
	5. Anti-asthmatics	147.20	3.76	269.46	7.94
	6. Analgesics	161.62	4.13	64.67	1.90
	7. Vitamins	201.93	5.16	268.16	7.90
	8. Cardiovascular	95.18	2.43	55.49	1.63
	9. Sulphas	2.02	0.05	3.96	0.11

Source: Indian Drugs Statistics 1982-83.

IPvtS can now be considered to have the technology to produce respectively 66.5 percent and 58.5 percent of the TNCs' bulk drug production as compared respectively to 76.8 percent and 68.6 percent previously, ie, when availability of technology were interpreted in a broader sense.

The Proportions of the bulk drug production of the TNCs for which technology may be considered to be no longer available are conspicuously larger in the case of the ISPvtS as compared with the ILPvtS and the PS. This implies that the bulk drugs which are not produced (or for which information is not available whether these are produced), but for which manufacturing plants are available, belong proportionately more to the ISPvtS than to the ILPvtS or the PS.

#### IS AND 'HIGH TECHNOLOGY' BULK DRUGS PRODUCED BY TNCs

At the level of technology, it can be argued that all the bulk drugs are not equally difficult to make. This leads to the consideration whether the bulk drugs produced by the TNCs, for which the IS does not have the technology, involve more complex processes or not. In connection with the implementation of the Foreign Exchange Regulation Act, 1973 (FERA), the government appointed a committee in 1978 to identify the bulk drugs involving "high technology" manufactured by the firms relevant to FERA, ie, those with a foreign equity of above 40 per cent. Out of the 32 TNCs manufacturing bulk drugs during 1976/76-77 and 1977/77-78, 27 firms had a foreign equity of above 40 percent and hence the manufacturing processes of the 171 bulk drugs produced by these 27 TNCs were considered by the committee. The remaining 21 bulk drugs, out of the total number of 192 bulk drugs produced by the TNCs, were produced by the remaining 5 firms with a foreign equity of 40 percent or below. The value of production of these 171 bulk drugs for which we have information about the nature of technology used is Rs. 711.7 million, ie, about 95 percent of the total production value of Rs 747.6 million. Therefore, to arrive at the following conclusions, it appears that we have used a good sample.

High technology has been used to produce 73 of the 171 bulk drugs produced by the TNCs. As Table 4 shows, there is no basis for believing that the incidence of high technology drugs is more in the group of drugs for which the IS does not have the manufacturing

Table—4

Technology Available with the IS to Produce "High Technology" Bulk Drugs Manufactured by the TNCs, During 1976/76-77 and 1977/77-78

	Total Number of Bulk Drugs	Number of Bulk Drugs out of Col (2) Examined to Find whether They Involve High Technology	Number of Bulk Drugs Involving High Tech- nology	Col (4) as a Percent of Col (3)
(1)	(2)	(3)	(4)	(5)
Total number of bulk drugs produced by TNCs, of which,	192	171	73	42.7
(A) Bulk drugs for which manufacturing technology is not available with the IS	79	69	26	37.7
(B) Bulk Drugs for which manufacturing technology is available				
(a) with the IPvtS	108	97	44	45.4
(b) with the PS	25	22	13	59.1
(c) Bulk drugs not produced by the IS	100	87	32	36.8
(D) Bulk drugs actually produced				
(a) by the IPvtS	88	81	39	48.1
(b) by the PS	17	14	8	57.1

Source See the Answer of the Government to question No 575, Rajya Sabha, New Delhi, April 27, 1981 (mimeographed) (for the names of bulk drugs involving high technology); the Text (section II) and Table 2.

technology. In fact, whereas 37.7 percent of the bulk drugs in this group involve high technology, the corresponding percentages for the bulk drugs for which the IPvtS and the PS have the technology are 45.4 percent and 59.1 percent respectively. The conclusion essentially remains the same even if we consider the bulk drugs

actually produced as the sole indication of the technology available with the IS (see the rows under (C) and (D) of Table 4).

### III. Formulation Production and Sales SECTORAL MARKET SHARES

The actual market shares of formulation sales by the different sectors have been calculated from the Operation Research Group's (ORG) market survey data. It provides national estimates of retail purchases for over 9,000 packings offered for sale by 150 leading drug companies. The information is collected from 544 chemists statistically selected to represent all the chemists in India. The products are classified into various therapeutic groups, which brings in competing products together. The grouping takes into account the therapeutic use, the body system where the drug acts, the composition, and the form of the drug.

The ORG data show that the TNCs dominate the formulation market, accounting for 60.2 percent of the total annual average sales of Rs.4,553.6 million during 1977 and 1978. The nearest rival is the indigenous private sector (IPvtS), which lags far behind with a 27.1 percent share. The joint ventures (JVs) cater to 11 percent of the market and the public sector (PS) a paltry 1.6 percent.

If we consider the sectoral market shares separately, in each of the product groups, some interesting features emerge. While the IPvtS lags far behind the TNCs in the aggregate, the former dominates the market in quite a few product groups. They control 50 percent or more of the market in 56 product groups, such as Intestinal absorbents (market share 100 percent), Ampicillin injection (99 percent), Narcotic analgesics (72 percent), Cough preparations (home products) (65 percent) PAS, INH combinations (55 percent), etc. For 40 product groups, their market share is as high as 70 percent or more. They are the sole sellers in 14 product groups.

The TNCs dominate a wider range of the market. For instance, in 174 product groups, such as Stomatologicals (market share 100 percent), Cardiac therapy (90 percent), Cold preparations (83 percent), Plain Vitamin A (73 percent), Antipruritic (57 percent), the TNCs control 50 percent or more of the market. What explains the overall dominance of the TNCs is not only that they dominate a wider range of product groups but also that they do so in general in the larger product groups compared to the IPvtS. Thus the average size of the markets where the TNCs control 50 percent or more of the

sale is worth Rs. 17.1 million. The corresponding size where the IPvtS controls 50 percent or more is worth Rs. 13.1 million.

The JVs, too, with an aggregate market share of only 11 percent, controls 50 percent or more of the sales in 13 product groups, the examples of which are Agents for syst fungal (100 percent), Streptomycin and combinations (79 percent), Iodine therapy (54 percent), etc. The performance of the PS in formulation sales is the poorest. Its market share is less than 10 percent in 29 out of the 33 product groups where it sells formulations. Its market share is highest in Synthetic hypotensives (37.78 percent). The PS actually lays more stress on the manufacture and sale of bulk drugs. It does not process into formulations the entire bulk drugs manufactured by it.

It must be added that the statistics provided by the ORG underestimate the shares of the IS since it considers only retail sales. It excludes direct institutional purchases made, for instance, by the Central and State Governments for use at hospitals and dispensaries. Such purchases are made through tenders under price competition. Hence, the proportion sold by the IS is expected to be larger compared to the TNCs, since the latter, in general, charge higher prices as discussed in Section VIII.

#### EXTENT OF TECHNOLOGY AVAILABLE WITH IS TO REPLACE TNCs' FORMULATION PRODUCTION

Unless the starting materials, the route, the precise reaction parameters (temperature, pressure, etc) etc, at every step of the process of manufacture are known, a bulk drug cannot be produced. In this sense, the processes of the different bulk drugs are different and the capability to produce a particular bulk drug does not by itself imply that other bulk drugs too can similarly be produced. Accordingly, in the previous section, actual production of a bulk drug by the IS was taken as an indication of the availability of manufacturing technology for that bulk drug alone.

In the case of formulations, however, the same method of production can be used irrespective of the active ingredients involved. Let us consider, for instance, the Wet Granulation method of tablet manufacturing. First, the active ingredient(s) mixed (or blended) with diluents (when the dose is too small for the tablet to be of a practical size) and with disintegrators (so as to facilitate the disintegration of the drug after administration). Then a binding solution is added by stirring. Thereafter, a granulator is used to form

Table—5

Formulation Sales by the IS in Products Groups Where the TNCs Sold During 1977 and 1978

	Number of Products Groups	Total Sales of the TNCs in the Product Groups Mentioned in Col (2)	Annual Average Percent (of the Value (in Rs    Total Sales) Million)
(1)	(2)	(3)	(4)
Number of products groups where formulations were sold by the TNCs, of which	241	2743.4	100.0
(a) Number of product groups where formulation were sold			
(i) by the ISPvtS	144	2232.3	81.4
(ii) by the ILPvtS	182	2584.2	94.2
(iii) by the ILPvtS	204	2672.3	97.4
(iv) by the PS	31	795.9	29.0
(v) by the IS	205	2675.4	97.5

Source. Calculated from ORG, "Retail Store Audit in Pharmaceutical Products"  
(Baroda, The Author, Annual), December, 1978.

distinct granules. These are dried and then reduced to specific particle sizes. The material is now ready to be compressed into tablets in a machine. In order to prevent adhesion of the material to the machine, lubricants are used before compression. By hanging the active ingredient(s) involved, but following the same steps as enumerated above, different types of tablets can be prepared. Thus, if the IS manufactures a particular type of tablet, then it follows that it can also manufacture other type of tablets involving other active ingredients. The same is true for other types of dosage forms such as solution, capsules, suspensions, ointments etc. Each has its own method(s) of manufacturing. But none is restricted to specific active ingredient alone. It may however, be added here that even for the same method of production, different types of machines and equipments are available, which may affect the cost of production, the speed of operations etc.

Each of the dosage form in which the TNCs process bulk drugs is also manufactured by the IS. Hence it follows from the above discussion that the latter has the technology to replace the entire formulation production of the TNCs. Let us, however, adopt a stricter criterion to examine what difference it makes if actual production by the IS in a particular product group is alone taken as an indication of the availability of manufacturing technology with the IS.

The government provides sector-wise but the product group-wise data on formulation production. We could not obtain data on the firm-wise (or sector-wise) and product group-wise formulation production from any other source. As a proxy, we will consider the ORG market sales data. In general, production and sales are correlated, the difference being explained by the adjustments in stocks. In the specific context of drugs, the sales of the IS underestimate its production. Under the loan licensing arrangements, as we shall discuss in the next section, the TNCs get drugs formulated in many cases by the IS, and then sell them under their own names. Again, the leading 150 drug companies considered by the ORG include 50 out of the 63 TNCs and 8 out of the 10 JVs manufacturing formulations. Hence, out of the total number of more than 1600 units in the industry, almost all the units excluded by the ORG belong to the IS. Their sales may be insignificant compared to those of the larger units. But nevertheless they do manufacture and sell a wide range of products.

However, even using sales as a variable, which underestimate the IS's formulation production and thus the manufacturing technology available with it, let us see to what extent it can replace the TNCs' formulation production. During 1977 and 1978, on an average, the TNCs sold formulations worth Rs. 2,143.4 million, spread over 241 product groups. The IS sold in 205 of these product groups, in which the sales of the TNCs amounted to Rs. 2,675.4 million. It follows from our criterion that the IS has the technology to produce, and thus replace 97.5 percent, i.e., almost the entire sales of the TNCs. The indigenous organised private sector (IOPs) alone can replace 94.2 percent, the indigenous non-organised private sector (INOPS) 81.4 percent and the PS, 29 percent (Table 5).

#### IV. Quality

As required under the Drugs and Cosmetics Act and Rules, drugs must conform to certain specific standards of identity, strength, purity and quality. Spurious and sub-standard drugs are prohibited by law from being manufactured and sold. It is the function of the Drug Control Administration to lay down standards and to control the quality of drugs.

However, the fact that a drug is manufactured and sold is no guarantee that it conforms to the standards laid down. The Central Drugs Laboratory, Calcutta analyses, among others, the samples of drugs collected from all over India (except those collected by the drug inspectors of Maharashtra, Gujarat and Tamil Nadu). In 1976 and 1977 it found 43.6 percent and 35.5 percent of the samples of drugs manufactured in India to be sub-standard. In Maharashtra, 13.2 percent and 12.4 percent of the samples turned out to be sub-standard in 1976-77 and 1977-78 respectively.

The names of the manufacturers of the sub-standard drugs are not divulged. Hence the information on the proportion of sub-standard drugs produced by the different sectors is not available. However, the findings in foreign countries, for instance the USA, where such data are available, show that it is not true that TNCs never manufacture and sell sub-standard drugs. Let us give a few examples: Sterile intravenous solution manufactured by Abbott were found to be contaminated by bacteria. Chlordiazepoxide tablets of Roche were adulterated. Richardson Merrell's (Richardson Hindusthan in India) Bactracin and Burroughs Wellcome's Polymixin B-Sulphate proved to be subpotent. Let us, however, assume for the sake of argument, that the TNCs never produce any sub-standard drugs in India (though we came across a case where they did so) and that all the sub-standard samples here were manufactured by the IS. Does it follow that all the units belonging to the IS produce sub-standard drugs? Or, in other words, that none of them is capable of producing drugs conforming to the proper standards? If it were really so, then all the products of the TNCs also would not have been of proper quality. The fact is that the TNCs do not operate in India as independent entities. As we shall discuss below, they depend on the IS for formulations and bulk drugs. Sales of drugs of proper quality by the TNCs reflex not only

the capability of the TNCs but also that of the IS to produce such drugs.

(a) *Loan Licensing*: Loan licensing is an interesting feature of the Drugs and Cosmetics Rules. The holder of a loan licence need not itself manufacture the related drugs. It is empowered to get the products manufactured by other firms and sell them under its own name. The TNCs have made widespread use of this provision of manufacturing under loan licence. The government in its New Drug Policy announced in 1978 decided to stop the grant of loan licences to the 'foreign companies', ie, those with a foreign equity of above 40 percent. The Organisation of Pharmaceutical Products of India (OPPI) (which is dominated by the TNCs) has objected to the abolition of loan licences to foreign companies. Interestingly enough, in the opinion of the OPPI, such licences should be continued "to meet local demands, *help Indian small scale units*, increasing exports and overcoming difficulties such as labour trouble, power cuts and so forth" (emphasis ours). This shows that the TNCs use the drugs manufactured by the ISPvtS to enlarge their sales. Again, All India Chemical and Pharmaceutical Employees Federation (AICAPEF) alleged that many drug firms did not manufacture the entire volume of their sales and this to do away with additional permanent jobs. It provides as an example, a list of six units belonging to the ISPvtS, which manufactured a number of drugs on behalf of a TNC, viz. Pfizer.

(b) *Purchase of bulk drugs by the TNCs to manufacture formulations*: The TNCs do not produce the entire bulk drugs they require for processing them into formulations. For 35 TNCs, which account for 89 percent of the total formulation sales of the TNCs, we found that they used Rs.238.5 million worth of imported drugs and Rs. 339 million worth of bulk drugs manufactured by other firms in India on an average during 1976/76-77 and 1977/77-78. These amounted to about 22.3 percent and 31.8 percent respectively of the total bulk drugs of Rs.1,067.3 million consumed by them. Their own production accounted for the remaining 45.9 percent. As we have already noted, 31 out of the 63 TNCs do not produce any bulk drugs at all. In this category are Abbott Laboratories, Smith Tune and French, Roussel Pharmaceutical, C Fulford etc.

Let us now consider whether it is possible that purchases of the locally manufactured bulk drugs by the TNCs are confined to them

none, ie, what one buys is sold by another TNC. Formulation production is generally considered to be more profitable compared to bulk drug production. It has been estimated that an exclusively formulation unit can recover its entire capital invested in a 2-4 year period. The ratio of capital invested to sales works out to be 1:2.6 on an average for formulation production in a number of units. It is rare for this ratio to exceed 1:1 in the case of bulk drugs. Naturally, therefore, those TNCs, which produce bulk drugs are not expected to sell them to others, be they TNCs or any other types of firms. The government, however, has started insisting on that manufacturers of bulk drugs must sell at least a part of their production. An analysis of the conditions imposed on the bulk drug licences given to the TNCs during 1972-79 reveal that the licenses are required to supply to the non-associated formulators 30-35 percent (or even more in the case of export obligation) of the bulk drug production of the new item or the additional production of the existing items. Probably, as a result of such measures undertaken by the government, 24 out of the 32 TNCs manufacturing bulk drugs sold 19.2 percent of Rs. 600.8 million worth of bulk drugs produced by them on an average during 1976/76-77 and 1977/77-78. No information is available, however, regarding the sales by the remaining TNCs, which contributed about 19.6 percent of the total bulk drug production of the TNCs. But they did not receive any licence during the period and hence the government measures were not applicable to them. Thus the proportion of their sales, if any, is likely to be less than 19.2 percent, the total sales of bulk drugs by the TNCs do not exceed Rs.143.5 million. Even if such sales are restricted within the TNCs, the total purchase of locally manufactured bulk drugs (at least Rs.339 million as noted above) exceeds the total sales by more than 136 percent. This shows that the TNCs do not make significant purchases from other sectors.

The volume of bulk drugs sold by the JVs is too small to satisfy the requirements of the TNCs. Bulk drugs manufactured by Sarabhai Chemicals, Sarabhai M Chemicals, Suhrid Geigy, Standard Pharmaceuticals and Synbiotics, are either not sold (as in the case of the first three companies or are entirely sold to Sarabhai Chemicals (as in the case of the last two). The remaining JVs, too, do not sell the entire volume of their bulk drug production worth Rs.75.1 million.

It follows that the TNCs depend on the IS to a significant extent for supply of bulk drugs. Since their inception, the PS units, HAL and IDPL, have been pursuing the policy of not formulating themselves the entire bulk drugs manufactured by them. But since formulation is more profitable, we should expect the IPvtS just like the TNCs to have the same tendency to process the bulk drugs themselves rather than to sell them to others. The units belonging to the IPvtS, which are more successful in the formulations market, in fact either do not sell any bulk drugs (eg, Dey's Medical) or sell only a small proportion (eg. Alembic, about 15 percent). Formulation market, however, is highly competitive. In comparison, selling most of the bulk drugs is not so much of a problem. Probably, as a result, a number of units in the IPvtS, especially those in the non-organised sector, have been found to concentrate on bulk drug production. The managing director of an indigenous firm, in fact, pointed out that formulation are easier to manufacture but more difficult to sell. Hence, they opted for bulk drug production. Manufacturers and sellers of bulk drugs also includes those which are primarily chemical firms and hence have no connection with formulations.

The fact that the IS supplies bulk drugs to the TNCs proves that if the bulk drugs used by the latter for manufacturing formulations conform to the official standards, then those manufactured by the IS must also do so.

### V. Bio-Availability

Even when they meet the officially prescribed standards of identity, strength, purity and quality, two or more drugs which are chemically equivalent (ie, they contain the same active ingredient(s) in identical amounts and dosage form) may have different bio-availability (ie, the rate at which the drug becomes available for absorption in the patient) and thus may be clinically (therapeutically) inequivalent (ie, the effect on the control of a symptom or disease may be different). A number of factors may cause the differences in bio-availability. As we have already pointed out in the context of our discussion on tablet manufacturing, active ingredients are combined with various other materials, eg, diluents, binders, lubricants, etc. The choice of these materials is the manufacturer's. Hence the tablets containing the same active ingredients manufactured by different firms may contain different types of these materials. Such differences in the composition may effect bio-availability. In extreme cases these

materials may interact with the active ingredients to nullify altogether the therapeutic effect. Another factor is the particle size of the drug which may also influence the rate of absorption of the drug.

If this is true, then the capability of the IS to produce a chemically equivalent drug does not appear to be enough to claim that they can replace the TNCs. But the question is how important is the factor of bio-availability? Is it true for all ingredients and all types of dosage forms? The Task Force on Prescription Drugs of the US Department of Health, Education and Welfare, which examined this question, concluded that:

on the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health.

The food and Drug Administration (FDA) of the USA, too, recognise the problem of bio-availability but its evaluations reveal that it is not present in every drug. As on 1981, 1,474 prescription drugs (both single ingredient and multiple-ingredient) were marketed in the USA, as approved by the FDA for safety and efficacy. Out of them, 499 products were sold by more than one firm. The FDA has evaluated whether such multiple source-drug products are therapeutically equivalent. Only in 86 products, ie, about 17 percent of the total products, chemical equivalence did not ensure therapeutic equivalence. The actual percentage, in fact, may be lower because in cases where adequate information or evidence were not available, the drugs were generally considered as inequivalents.

Not much work has been done specifically regarding the bio-availability of drugs manufactured in India. A group of Pharmacologists at the Bombay College of Pharmacy and the Grant Medical College, Bombay have done a few studies. They selected a few drugs for which the problem of bio-availability might be anticipated and tried to find out whether it was actually present in products manufactured in India. For some drugs, such as Phenytoin, Phenylbutazone, Indomethacin and Tetracycline, wide differences in the bio-availability had been observed among the chemically equivalent formulations manufactured by different firms. But for some other drugs such as Tolbutamide, Chlorpropamide, Chlorpromazine and Nitrofurantoin, no significant differences in bio-availability were found and hence the products of the different

manufacturers could be treated as bio-equivalent. This names of manufacturers considered by the authors have been divulged in only two cases—Chlorpropamide and Nitrofurantoin. In both the cases, tablets manufactured by four firms belonging to the IPvtS including the ISPvtS were found to be bio-equivalent to the tablet manufactured by a TNC. This clearly shows that it is possible for the IS to manufacture drugs bio-equivalent to those manufactured by the TNCs. Hence, unless bio-inequivalence is proved, production of chemically equivalent drugs by the IS may be considered to be a sufficient indication of its capability to replace the TNCs as discussed above.

### VI Cost of Production

We have not been able to obtain any cost data on formulation production. Regarding bulk drugs, we have succeeded in only six cases, the cost data for which are provided in Tables 6 to 11. In each of these cases the IS has developed manufacturing technologies on its own, ie, without any foreign assistance. It may be observed that for four bulk drugs—Isonicotinic acid hydrazide (INH), Chlorpropamide, Metronidazole and Amodiaquin, the indigenous firms are more efficient than the TNCs in terms of the cost of production. For the remaining two drugs—Dapsone and Chloroquin Phosphate—the costs of production of the TNCs are lower (cf cols (2) and (3) of the respective tables).

The costs, however, do not refer to the same period. The gap between the periods of costing varies between three and eight months (Tables 6-11). Let us, however, try to analyse whether the nature of the cost differential would have changed if actual costs referred to the same period.

In the case of Dapsone, the cost of production of the indigenous firm exceeds that of the TNC by about Rs. 252 per kg. ie, by about 231 percent (cf cols (2) and (3), of Table 6). Even if the cost changes in favour of the indigenous firms, it is unlikely for such a large cost differential to be eliminated in course of the five months. ie, the difference between the periods of costing of the two firms.

In the case of INH, for which the indigenous firm is more efficient, utilities and conversion cost account for about 97 percent of the difference in the total cost of the indigenous firm and that of the TNC (col (4) of Table 7). The prices of the utilities (eg. the rates of electricity) have a tendency to increase rather than decrease over

**Table-6**  
**COST OF PRODUCTION OF DAPSONE**  
*(Figures in Rs. per kg and percent)*

Period of Costing	Actual Cost			Estimated Cost <sup>a</sup>	
	A TNC	An Indi- genous Firm	Actual Cost Differential Col (3)-Col (2)	TNC	Indigen- ous Firm
	Year	Year		As on	As on
	Ending Aug. 1976	Ending Mar 1976		July 1977	July 1977
(1)	(2)	(3)	(4)	(5)	(6)
1. Raw material (a + b)	42.31	185.61	143.3 (56.8)	37.13	180.61
a) Imports	2.64	—	2.64 (-1.0)	2.38	—
b) Local	39.67	185.61	145.94 (57.8)	34.75	180.61
c) Imports as percent of total	6.2	—		6.4	—
2. Utilities	22.45	29.76	7.31 ( 2.9)		
3. Conversion cost(a to f)	44.37	146.21	101.84 (40.3)		
a) Salaries & Wages	9.08	35.04	25.96 (10.3)		
b) Repairs, mainte- nance and stores	5.78	10.03	4.25 ( 1.7)		
c) Depreciation	4.08	2.16	-1.92 (-0.8)		
d) Administrative overheads	4.87	13.71	8.84 ( 3.5)		
d) Factoryoverheads <sup>b</sup>	20.56	106.70	86.14 (34.1)		
f) Less: Credit for by product	—	21.43	-21.43 (-8.5)		
4. Total cost of production (1 to 3)	109.13	361.58	252.45 (100.0)		

*Note:* Figures in the brackets in col (4) are percentages to the total cost differential.  
 \* The costs in cols (5) and (6) have been estimated on the basis of the actual raw material prices and the parameters of raw material consumption as technically assessed. Hence these may be considered as actuals for the relevant period.

\* Research and Development expenditure wherever incurred has been included under **Factory overheads**.

*Source:* Information obtained confidentially from an official source.

time. Similarly, the volume of production remaining the same, conversion cost tend to rise, given the normal growth in salaries and

**Table 7**  
**Cost of Production of Isonicotinic Acid Hydrazide (INH)**

(Figures in Rs per kg and per cent)

Period of Costing (1)	Actual Cost		An Indigenous Firm Year Ending March 1978 (3)	Actual Cost Differential (Col (2)-(Col (3)) (4)	Estimated Cost	
	A TNC Year Ending Nov 1977 (2)				TNC As on Oct 1979 (5)	Indigenous Firm As on Oct 1979 (6)
1 Raw material cost (a + b)						
a) Imports	77.51		75.06	2.45 (3.4)	117.63	100.43
b) Local	a			—	a	—
c) Imports as per cent of total	a		75.06	—	a	100.43
2 Conversion cost	11.11		0.98	10.13 (14.0)		
3 Conversion cost (a to f)	95.00		35.00	60.00 (82.6)		
a) Salaries & wages	40.75		3.63	37.12 (51.1)		
b) Repairs, maintenance and stores	14.00		1.59	12.41 (17.1)		
c) Depreciation	17.28		1.27	15.01 (20.7)		
d) Administrative overheads	10.23			10.23 (14.1)		
e) Factory overheads	12.74		2.30	10.44 (14.4)		
f) Outside engineering charges			25.21	—25.21 (—34.7)		
4 Total cost of production (1 to 3)	183.62		111.04	75.58 (100.0)		

Note: a) The TNC uses imported raw materials, but information on the amount is not available. Other notes are same as in Table 6.  
 Source: Same as in Table 6.

wages, administrative expenses etc. The TNC's period of costing is four months earlier. Within the intervening period, therefore, its cost is likely to increase, if at all it changes. It follows, therefore, that the possibility is for the cost differential between the indigenous firm and the TNC to diverge further, ie, the former to remain more efficient.

All the components of cost, viz, utilities, conversion cost and raw materials are important in explaining the difference in the cost of manufacturing Chlorpropamide by the indigenous firm and the TNC (Col(4) of Table 8). The utilities and the conversion cost of the TNC have remained stable for two successive years ending November 1978 and 1979. The difference is only Re. 0.89 per kg. Hence if the TNC's utilities and conversion cost are taken for the year ending March 1979 (ie, the same as the indigenous firm's period of costing) rather than November 1979, then these costs are not expected to change. On the other hand an increase has been observed in the prices of the raw materials. The raw material cost of the TNC for the year ending November 1979 is Rs. 120.00 per kg against Rs. 88.81 the previous year. Thus its raw material cost for the year ending March 1979 will be somewhere in between, ie. above the indigenous firm's raw material cost of Rs. 65.52 per kg for the same period (cols (2) and (3) of Table 8). It follows that even if we take the same period of costing for both the firms, the indigenous firms will continue to be more efficient.

Regarding the remaining three bulk drugs—Metronidazole, Amodiaquin and Chloroquin Phosphate—the raw material cost is the dominant factor explaining the cost differential (col (4) of Table 9-11). Therefore, whether the relative efficiency will be reversed if costs referred to the same period will depend primarily on the variation in the raw material prices.

The raw material cost of the TNC's production of Metronidazole during the year ending December 1977 is more than double that of the indigenous firm's during the year ending June 1978 (cf cols (2) and (3) of Table 9) The prices of raw materials used by the indigenous firm have a rising tendency. Hence if its costs were calculated for the year ending December 1977 (ie the same as the TNC's period of costing) rather than June 1978, then the raw material cost would have been lower so that the cost differential would have been still larger.

In the case of Amodiaquin too, as Table 10 shows, the TNC's



raw material cost for the year ending November 1978 is higher than that of the indigenous firm for the year ending March, 1978. But to make the costs comparable, if the indigenous firm's costs are also considered for the year ending November 1978, ie, a later period, then its raw material costs will be higher because the trend in the prices of its raw materials is upward. Whether it will rise sufficiently to reverse the cost differential is uncertain since the extent of the rise in prices is not known.

The prices of the raw materials used by the TNC to manufacture Chloroquin Phosphate remained stable between the year ending December 1977 (ie, the TNC's period of costing) and the year ending March 1978 (ie, the indigenous firm's period of costing). Hence, if we consider the year ending March 1978 as the common period of costing, the relative efficiency of the TNC will be maintained (Table 11).

It follows from the above discussion that the indigenous firms may be considered as more efficient in manufacturing three out of the six bulk drugs considered and the TNCs in two drugs. The outcome of the remaining one is uncertain. Our sample is too unrepresentative to justify any general observation regarding the relative efficiency of the two sectors as a whole. But our examples do demonstrate that the TNCs are not necessarily more efficient, and that it is possible for the IS to produce bulk drugs at a lower cost compared to the TNCs. Hence, in the case of the remaining bulk drugs produced by both the TNCs and the IS, the latter, unless otherwise proved, need not be considered as less efficient.

### VII Over-pricing

Over-pricing of imported materials by the TNCs in India has been reported from time to time. For example, an indigenous firm imported Chlordiazepoxide at Rs. 312 per kg. But Roche were importing the same drug (brand name: Librium) at Rs. 5,555 per kg. ie, at a price 1,680 percent higher. Similarly, another TNC imported Indomethacin at Rs.3,400 per kg, which was 844 percent higher compared to Rs. 360 per kg at which it was available in the international market. (For four other examples see Table 12).

Dexamethasone used to be imported by a TNC at Rs.60,000 per kg. Due to the intervention of the Controller of Imports, the price was reduced to Rs.16,000. When cheaper sources of imports of drugs

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**Table—9**  
**Cost of Production of Metronidazole**

(Figures in Rs per kg and per cent)

Period of Costing	Actual Cost		An Indigenous Firm Year Ending June 1978	Actual Cost Differential (col (2)-Col (3)) <sup>1</sup>	Estimated Cost	
	A TNC Year Ending Dec 1977	TNC As on Oct 1979 and April 1980 (5)			Indigenous Firm As on Oct 1979 and April 1980 (6)	
(1)	(2)	(3)	(4)	(5)	(6)	
1 Raw material cost (a + b)	437.49	214.64	222.85 (85.8)	306.39	318.22	
a) Imports	235.85	62.79	173.06 (66.6)	51.68	93.12	
b) Local	201.64	151.85	49.79 (19.2)	254.71	225.10	
c) Imports as per cent of total	53.9	29.2		16.20	29.30	
2 Utilities	33.99	15.37	18.62 (7.2)			
3 Conversion cost (a to e)	184.16	165.78	18.38 (7.1)			
a) Salaries & wages	84.24	17.79	66.45 (25.6)			
b) Repairs, maintenance and stores	41.47	10.33	31.14 (12.0)			
c) Depreciation	11.01	65.83	54.82 (21.1)			
d) Administrative overheads	36.59	31.96	4.63 (1.8)			
e) Factory overheads	10.85	39.87	29.02 (11.2)			
4 Total cost of production (1 to 3)	655.64	395.79	259.85 (100.0)			

Source & Notes: Same as in Table 6

were detected, the government under the Import Trade Control Policy put a ceiling on the import prices. During 1960-61 to 1974-75, the government specified the maximum c i f import price at which imports would be allowed for 23 bulk drugs (as listed in Table 13).

In a recent paper, C.P.Chandrasekhar and Prabir Purkayastha have provided an estimate of over-pricing by the TNCs. They considered 70 percent of imports of 29 "foreign drug companies" during 1972-76, worth Rs.1,329.49 lakhs and compared the prices paid by these companies to their "parent or affiliate" with the minimum prices at which the same material was actually imported. As the authors point out, this obviously led to an under-estimation of over-pricing because the same material could have been available at lower prices in the international market. For all the materials combined, the average extent of over-pricing was found to be 126.52 percent. They however, did not provide any product-wise or firm-wise information on over-pricing.

A Committee under the Chairmanship of L. Kumar was appointed by the Ministry of Petroleum, Chemicals and Fertilisers in 1978 "to investigate into allegations of unduly large profits by foreign drug companies". The Report of the Committee has not yet been published. We got access to the data collected by this Committee and would use them in order to discuss the implications regarding over-pricing.

Before we deal with the import prices, it may be interesting to have an idea about the extent of intra-firm trade, ie, trade between a firm and its parent (ie, which controls the former) or between sister firms (ie, which are controlled by the same parent firm). Table 14 shows the extent to which the major imports (ie, those accounting for at least 70 percent of the import bill) of 28 companies in India come from their associates / collaborators. The collaborators owning more than 50 percent of equity are obviously the parents of the representative units. But the associates or the collaborators, even with less than 50 percent of equity effectively control the units either solely or jointly with Indian firms / groups (in the case of joint ventures). Hence, imports from associates / collaborators give an idea about the extent of intra-firm trade. It may be observed from Table 14 that 52.6 percent of the major imports of 28 companies are supplied by the respective associates / collaborators. Hence, intra-firm trade is significant enough to provide the TNCs the



opportunities to manipulate the prices of such transactions. The extent of such trade, however varies from company to company. At one extreme are Uni-Sankyo, J.L. Morison, Son and Jones and John Wyeth & Bros, which import the entire requirements from their associates/collaborators. At the other extreme are Martin & Harris, Beecham, Anglo French and Carter Wallace, which do not at all depend on the associates/collaborators. Among the top 10 TNCs opening in India, Burroughs Wellcome and Sandoz buy more than two-thirds of their imports from associates/collaborators; Glaxo and Ciba Geigy around a half; Pfizer around one-third; Boots around a quarter and E. Merck and Parke Davis a significantly lower proportion of 5.7 percent and 14.4 percent respectively (Table 14).

To come to the question of import prices, the basic data include (a) importing company; (b) source of imports; (c) quantity purchased and (d) c i f value of imports, of 36 selected raw materials, intermediates and bulk drugs imported by 26 companies during 1972/72-73 to 1977/77-78. The total value of imports of materials covered by the sample is Rs. 236.41 lakhs. Our sample, while smaller than Chandrasekhar and Purkayastha's, will enable us to estimate product-wise and firm-wise over-pricing of imports.<sup>88</sup>

The data reveal that the prices of the materials imported in the same year vary, depending on the importing company and the source of imports. In Table 15 we have listed 15 out of the 36 materials each of which was bought by at least one company from its parent/sister company and which at least one other company imported in the same year from a non-parent/sister source. We have compared the import prices of the intra-firm transactions (col. 6) with the minimum prices at which the same materials in the same year were imported from other sources (col 7). The comparison reveals that in 24 out of the 35 transactions, the companies concerned imported the materials from their parent/sister companies at a price higher than at which these were available from other sources. This confirms the practice of overpricing by the TNCs. In the remaining 11 cases also, in which the parent/sister companies were the cheapest sources, overpricing may not be ruled out. This is because the 26 companies in our sample restricted their purchases of 36 materials to only 58 sources including their parent/sister companies. We do not have any information on the prices at which other sources would have supplied the same materials. It is possible that they would have done at lower prices.



The extent to which the prices paid for the intra-firm transactions exceed the corresponding minimum prices, varies between 4.14 percent (in the case of Butyl Hydroxy Anisole imported by Glaxo in 1973) and 338.68 percent (Veegum by Abbott in 1975). In one other case, the over-pricing is more than 300 percent. It lies between 100 and 300 percent in 6 transactions; between 50 and 100 percent in 6; between 10 and 50 percent in 7 and below 10 percent in 3 transactions (col. 8 of Table 15). In order to find the extent of over-pricing for all the products combined, Chandrasekhar and Purkayashita took the average of the over-pricing in individual cases, using the corresponding value of imports as the weights. But it is difficult to understand the rationale of this method. Price is the expenditure for a unit of a commodity. Hence, over-pricing, measured as the difference between the actual price and the minimum price as a percent of the latter, basically shows the excess expenditure as a percent of the minimum expenditure for a unit of the commodity. Similarly, the excess expenditure as a percent of the minimum expenditure for all the commodities combined, should be considered as the aggregate over-pricing. The actual value of imports for all the materials listed in Table 15 is Rs.9,01,652 (col. 5). If the same quantities (col. 4) were purchased at the minimum prices (col. 7) then the total expenditure would have been Rs. 5,40,577 (col. 9). The excess expenditure of Rs.3,61,075 as a percent of the minimum expenditure (Rs.5,40,577) i.e. 66.8 percent. This may be considered as the aggregate over-pricing. To the extent the materials were available at lower prices in the international market, the percent over-pricing, obviously, would have been higher.

So long we have implicitly assumed that non-parent sister sources abroad are unrelated. This is not necessarily true. Secret arrangements of various types between two independent companies are not unknown. It is possible, for instance, for Pfizer in India to import from Abbott in USA at a higher price through mutual agreement. This may be in exchange for over-priced imports by Abbott in India or any other deal. The companies may resort to such indirect over-pricing for a number of reasons. Over-pricing through intra-firm transactions, for instance, may not be possible when the companies concerned do not manufacture the goods to be traded. Again, when opportunities of indirect overpricing are there, it may be preferred to direct transfer pricing, the risk of exposure and

**Table —12**  
**Over Pricing of Imports of Selected Bulk Drugs by the TNCs in India**

Name of the Bulk Drugs	Unit	The Price at which the TNCs Imported in India (Rs)	International Market Price (Rs) <sup>1</sup>	Over-Pricing <sup>2</sup> (Per Cent)
(1)	(2)	(3)	(4)	(5)
1 Chlordiazepoxide	Kg	5555	312	1680.4
2 Vitamin B 12	Gram	230	90-100	130-155.5
3 Indomethacin	Kg	3400	360	844.4
4 Prenylamine lactate	Kg	1900	470	304.2
5 Fursamide	Kg	1650	520	217.3
6 Erythromycin	Kg	1200	780	53.8

Notes: <sup>1</sup> : Price at which other firms offered the product. It is not necessarily the minimum price in the international market.

<sup>2</sup> :  $\text{Col (3) - Col (4)} \times 100 / \text{Col (4)}$

Sources: For row 1, evidence of Hasmukhalal C Shah, Pharmaceutical Manufacturers Organisation, Ahmedabad, *Joint Committee on the Parents Bill 1965. Evidence* (New Delhi, Lok Sabha Secretariat, 1966), Vol II, p 628.  
 For row 2 P L Badami, "Need for Early Enactment", in *Commerce*, May 4, 1988 p 13, cited in Jawaharlal Nehru University and Indian Council of Scientific and Industrial Research, "Case Studies in the Transfer of Technology: The Pharmaceutical Industry in India" (mimeographed, n p UNCTAD, 1977) p 32. For rows 3 to 6, Swaminathan S Aiyar, "Govt to End Muleting by Foreign Drug Units", in *Times of India*, New Delhi, 7 April, 1975.

retaliatory action by the government concerned being less. However, due to lack of information, we could not estimate the extent of over-pricing due to such arrangements. It may be noted that compared to 15 materials considered in Table 15, in 14 out of the 36 materials covered in our sample, all companies imported from independent companies. In the remaining 7 cases, all the companies imported from their respective parents/sisters. Here, too, we could not estimate the extent of over-pricing, if any, because all these prices are transfer prices and no market prices were available with which to make a comparison.

The import prices in our sample have been observed to vary not

only between parent/sister companies and non-parent/sister companies but also between various non-parent/sister companies. There are, in fact, instances of the same company in India importing from different sources at different prices. Some sources also supplied the same materials in the same year at different rates. Assuming that there are no arrangements between independent companies, it only shows that import prices also vary due to factors other than transfer pricing. Hence, depending on the source, an indigenous firm too, for instance, may land up paying more than the minimum price in the international market. But even if in a particular transaction it pays more, it is not expected to do so whenever it can buy from a cheaper

**Table—13**

A List of Bulk Drugs with Ceiling on CIF Import Prices Under  
Import  
Trade Control Policy 1960-61 to 1974-75

- 1 Chloramphenicol
- 2 Hydrochlorthiazide
- 3 Hydroxy Progesterone
- 4 Norethynodrel
- 5 Norethisterone
- 6 Chlorpropamide
- 7 Chlorpromazine
- 8 Chlorthiazide
- 9 Ethionamide
- 10 Neomycin Sulphate
- 11 Phenformin
- 12 Polimyelitis Vaccine (Sabin)
- 13 Polimyelitis Vaccine (Salk)
- 14 Pyrazinamide
- 15 Sulphadimethoxine
- 16 Sulphafurazole
- 17 Sulphaphenazole
- 18 Thioridazine
- 19 Tolbutamide
- 20 Trifluoperazine
- 21 Chlordiazepoxide
- 22 Dexamethasone
- 23 Diazepam

*Note:* The ceiling was imposed by the government at least once for each of these drugs during 1960-61 to 1974-75.

*Source:* Compiled from GOI, Import Trade Control Policy, (New Delhi, Ministry of Commerce, Annual), Appendix 19 (relevant years).

Table—14

Major Imports<sup>1</sup> of Raw Materials, Intermediates and Bulk Drugs from Associates/ Collaborators by 28 Companies in India. 1977

Name of the Company	Major Imports from Associates/ Collaborators	Major Imports from all Sources	Col (2) as a Per Cent of Col (3)
(1)	(2)	(3)	(4)
1 Abbot Laboratories (India)	3.76	6.91	54.4
2 Wyeth Laboratories	14.62	28.35	51.7
3 Burroughs Wellcome & Co (India)	92.83	128.82	72.1
4 Smith, Kline & French (India)	32.4	47.70	67.2
5 US Vitamins & Pharmaceuticals	4.81	10.83	44.4
6 Uni-Sankyo	2.66	2.66	100.0
7 Richardson Hindustan	1.86	2.58	72.1
8 Suhrid Geigy	6.34	21.85	29.0
9 Organon (India)	17.49	20.53	85.2
10 Martin & Harris	—	6.55	—
11 J L Morison, Son & Jones (India)	0.07	0.07	100.0
12 Duphar Interfran	51.86	53.66	96.6
13 Beecham (India)	—	2.95	—
14 Bayer (India)	61.12	87.75	69.6
15 Ciba Geigy of india	16.45	33.37	49.3
16 Pfizer	13.91	40.40	34.4
17 Sandoz (India)	129.00	156.00	82.7
18 Geoffrey Manners & Co	12.71	29.34	43.3
19 Glaxo Laboratories (India)	62.34	133.50	46.7
20 John Wyeth & Bros	9.24	9.24	100.0
21 Boots Co (India)	28.34	121.51	23.3
22 E Merck (India)	2.18	37.99	5.7
23 Roche products	71.15	149.24	47.7
24 Anglo French Drug Co (Eastern)	—	8.87	—
25 Parke Davis (India)	5.94	41.11	14.4
26 Carter Wallace	—	18.95	—
27 Warner Hindusthan	1.57	32.67	4.8
28 May & Baker	62.34	105.33	59.2
Total	704.63	1338.73	52.6

Note <sup>1</sup> Major imports refer to at least 70 per cent of the total import bill for each company.

Source: See text (Section VII).

source. In contrast, in the case of the TNCs it is a matter of corporate strategy whether a company in India will buy from the cheapest source known to it or at a higher price from its parent/sister companies.

Before concluding this section, let us mention that the TNCs in India (and also the indigenous firms) are not permitted to import directly all of their requirements. In 1970-71, the government adopted the policy canalisation of imports of certain drugs through a public sector agency (State Trading Corporation). Canalisation, however, does not necessarily imply that the import prices will be lower. In the case of Vitamin B for instance, the two suppliers, which monopolised the international market, refused to supply it at a lower price to the STC. Canalisation, however, does ensure that the cost of imported materials will be the same for all the users, including the TNCs. But the drugs to be canalised vary from year to year and in a particular year cover only a segment of the total imports. During 1978-79 to 1980-81, for instance, only 39 bulk drugs and drug intermediates were canalised through the State Chemicals and Pharmaceuticals Corporation of India (a subsidiary of STC) in contrast to at least 532 imported by the country as a whole. Again, canalisation has not always succeeded in stopping direct imports by the TNCs. In some cases, as in the case of Methyl Dopa, a TNC, viz, Merck Sharp and Dohme, refused to accept the supplies from East European sources. The government permitted it to import from its parent company.

Over-pricing of imports by the TNCs in India has an important implication as far as the question of relative efficiency is concerned. It shows that the TNCs may not produce in India at the lowest cost at which they are capable of doing. Even if we assume that the TNCs have the capability to produce drugs at a lower cost compared to the indigenous firms, the cost of production of the former, in fact, may be higher if the extent of over-pricing is sufficiently high to out-weigh the cost advantages that the TNCs otherwise may have.

### **VIII Formulation Prices**

Bulk drugs are the raw materials for formulation production. Those firms which are successful in selling formulations (as the TNCs and a segment of the IS are) have a tendency to use the bulk drug manufactured by them for their own use rather than to sell it to other formulators. In such cases, obviously, the question of comparing

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**Table — 15**  
Over Pricing of Imports of 15 Materials by Selected TNCs in India

Name of the Imported Raw Material, Intermediate or Bulk Drug	Name of the Importing Company	Year	Imports from Parent or Sister Companies Quantity (Kg)	Parent Value (Rs)	Import Price (Col (5) Col (4) (Rs)	Minimum Import Price <sup>1</sup> (Rs)	Over-Pricing <sup>2</sup> (percent)	Value of Imports if Purchased at Minimum Price (Col(4) * Col (7) (Rs)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1 Neomycin Sulphate	Pfizer	1972-73	180	72648	403.60	171.79	134.94	30922.20
	Burroughs	1973-74	125.54	49950.75	374	250.66	49.21	31467.85
	Wellcome							
	Pfizer	1973-74	40	17069.20	449.23	250.66	79.22	10026.40
	Burroughs							
	Wellcome							
	Welcome	1974-75	110.28	61516.40	557.82	325.73	71.25	35921.50
	Pfizer	1974-75	146	116600.46	798.63	325.73	145.18	47556.58
	Pfizer	1975-76	221	197337.88	892.93	400.65	122.87	88543.65
2 Kaolin light	May & Baker	1972-73	1250	4706	3.76	2.25	67.11	2812.50
	May & Baker	1973-74	1600	6008	3.76	2.17	73.27	3472
	May & Baker	1974-75	775	3176	4.10	2.76	48.55	2139
3Cellulose Acetate Phthalate	Glaxo	1975-76	70	12114	173.07	109.41	58.18	7658.70
4 Ethyl Vannilin	Glaxo	1976-77	50	12661	253.22	174.68	44.96	8734
5 Cremophor EL	E Merck	1976	200	9409	47.05	20.88	125.34	4176
	E Merck	1977	300	15672	52.24	22.99	127.23	6897
6 Butyl Hydroxy Anisole	Glaxo	1973	100	800.42	80	76.82	4.14	7682

7 Caffeine Anhydrous	Glaxo	1977	700	56784	81.12	60.89	33.22	42623
8 Dimethyl Formamide	Wyeth	1975	1859.7	13761.78	7.40	7.15	3.50	13296.86
	Wyeth	1976	1116	12881	11.54	7.71	49.68	8604.36
9 Bentylnonium Chloride	Glaxo	1973	45	1948.95	43.31	43.31	—	1948.95
10 Phenylphrine Hcl	Glaxo	1974	8	6741.04	842.63	670.96	25.58	5367.68
	Glaxo	1975	5	4237	847.40	847.40	—	4237
	Glaxo	1976	5	4434	886.80	886.60	—	4433
	Glaxo	1977	7	7017.01	1002.43	1002.43	—	7017.01
11 Ephedrine Hcl	May & Baker	1974	150	41355	275.70	275.70	—	41355
12 Veegum	Geoffrey	1974	91	6289	69.11	35.90	92.51	3266.90
	Manners							
	Abbott	1975	300	23545	78.48	17.89	338.68	5367
	Geoffrey	1975	136.06	9952	73.14	17.89	308.83	2434.11
	Manners							
	Geoffrey	1977	181.52	16319	89.91	42.13	113.42	7647.44
	Manners							
13 Theophylline Anhydrous	May & Baker	1973	125	6935	55.48	55.48	—	69.35
	May & Baker	1974	100	5239	52.39	52.39	—	5239
	May & Baker	1975	50	3115	62.30	62.30	—	3115
	May & Baker	1976	120	9131	76.09	69.96	8.76	8395.20
14 Amylobarbitone	May & Baker	1975	140	19462	139.01	139.01	—	19462
	May & Baker	1976	165	25916	157.07	157.07	—	25916
	May & Baker	1977	150	21065	140.43	140.43	—	21065
15 Bismuth Glycyon	Jon Wyeth	1974-75	85	20754	244.16	174.60	39.84	14841
Arsanilate	& Bros							
Total				901652				540577

Notes: 1. The minimum price at which other companies imported the same material in the same year from non parent/sister companies.

2 : Col (6)-Col (7) × 100/Col (7)

Source: See text (Section VII).

**Table—16**  
Comparison of Retailer's Prices of the TNCs and the IS in 1978

Nature of Price Difference <sup>1</sup>	Extent of Price Difference (Percent) <sup>2</sup>	Number of Products	Generic Names of the Products
(1)	(2)	(3)	(4)
1 Price of TNC higher than maximum price of IS	Above 200	4	Betamethasone, 0.5 mg; Chlorpromazine, Hcl, 25 mg; Hydrochlorothiazide, 50 mg; Hydrochlorothiazide, 25 mg.
	100-200	2	Chlorthalidone Sulphate, 200 mg; Diethylcarbamazine, 50 mg.
	50-100	2	Methergometrine Maleate, 0.125 mg; Phenitamine Maleate, 22.5 mg.
	Less than 50	4	Basacodyl, 5 mg; Dimethinden Maleate, 7 mg; Phenitamine Maleate, 45 mg; Tolbutamide, 1 gm.
2 Price of TNC lower than maximum price of IS but higher than minimum price of IS	Above 200	7	Ascorbic acid, 500 mg; Chlorpromazine Hcl, 10 mg; Diphenhydramine HCl, 50 mg; Diethylcarbamazine Citrate, 50 mg; Metronidazole, 200 mg; Progesterone, 25 mg; Testosterone Propionate, 25 mg.
	100-200	9	Analgin, 0.5 mg; Acetazolamide, 250 mg; Chlorpropamide, 100 mg; Chlorpropamide 250 mg; Diphenhydramine, Hcl, 25 mg; Paracetamol, 500 mg; Sulphadiazine, 0.5 mg; Sulphaguanidine, 0.5 gm; Tolbutamide, 0.5 gm.
	50-100	14	APC; Ascorbic acid, 100 mg; Benzyl Benzoate, 25 per cent; Chloramphenicol, 250 mg; Digoxin, 0.25 mg; Isoniazide, 100 mg; Oxytetracycline Hcl, 250 mg; Prednisolone, 5 mg; Prochlorperazine, 25 mg; Phenobarbitone 60 mg; Phenytone Sodium, 100 mg; Quinidochlor, 6.25 gm; Saccharin, 12 mg; Tetracycline Hcl, 250 mg;

	Less than 50	8	Chloramphenicol Streptomycin Sulphate; Griseofulvin, 125 mg; Isomazide, 50 mg; Nikethamide 25 per cent, 2 ml; prochlorperazine, 5 mg;
3. Price of TNC lower than minimum price of IS	Less than 50	4	Phenobarbitone, 30 mg; Sulphasomidine, 0.5 gm; Sulphaphenazole, 0.5 gm
Total		54	Chloramphenicol Streptomycin Sulphate (Suspension); Glibenclamide 5 mg; Insulin Protamine Zinc, 40 units; Testosterone Propionate 50 mg

*Note:*

1. For the details of the Prices of the TNCs and the maximum and minimum prices of the IS, see Sudip Chaudhuri, "Indigenous Firms in Relation to the Transnational Corporations in the Drug Industry in India," (Doctoral thesis submitted to the Jawaharlal Nehru University New Delhi, February, 1984), Table 6.12.

2. The absolute difference between the price of the TNC and the minimum price of the IS as a per cent of the latter

Source: Information on prices obtained from *Indian Pharmaceutical Guide*, (New Delhi, Pamposh Publications, Annual), 1978

**Table—17**  
**Price Difference Between TNCs and Indigenous Firms in**  
**1978 and 1982**

Nature of Price Difference	Extent of Price Difference (Per Cent)	Number of Products <sup>3</sup>	
		1978	1982
(1)	(2)	(3)	(4)
1 Price of TNC <sup>1</sup> higher than that of indigenous firm <sup>2</sup>	Above 200	4	4
	100-200	6	5
	50-100	13	13
2 Price of TNC <sup>1</sup> lower than that of indigenous firm <sup>2</sup>	Less than 50	15	16
	Less than 50	6	7
3 Price of TNC <sup>1</sup> equal to that of indigenous firm <sup>2</sup>		1 <sup>4</sup>	—
Total		45	45

*Notes:* <sup>1</sup> : Same TNCs as considered in Table 16

<sup>2</sup> : Same indigenous firms which charged the minimum price as considered in Table 16. Where information on prices for these firms were not available for 1982, we have chosen the next indigenous firm (in terms of prices in 1978 for which such information were available).

<sup>3</sup> : for the details of the names and the prices of the products, see Sudip Chaudhuri, "Indigenous Firms in Relation to the Transnational Corporations in the Drug Industry in India" (Doctoral these submitted to the Jawaharlal Nehru University, New Delhi, February, 1984). Table 16.

<sup>4</sup> : In 1978, the price of the TNC was actually higher than that of the indigenous firm which charged the minimum price for this product (Prochlorperazine, 25 mg.). But price data for this indigenous firm (see note 2 above), the price of the TNC was the same in 1978 and higher in 1982.

*Source:* Same as in Table 16, 1978 and 1982.

bulk drug prices does not arise. Moreover, we have not been able to obtain information on the prices of those bulk drugs which are sold to others. Hence we will compare here only the prices of formulations.

### PAST STUDIES

Agarwal, Ramachandran and Rangarao compared the prices of different manufacturers in 1972 for "a sample of 19 widely used drugs." The retail prices varied a great deal and some indigenous firms did charge prices higher than those of the TNCs. But, on the whole except for APC tablets each of the remaining 18 formulations

were available from the IS at a price lower than the minimum price charged by the TNCs (subsidiaries). The minimum prices were the same for both the sectors in the case of APC tablets. The price differences were not uniform. The minimum price of the TNCs exceeded that of the IS by about 11 percent in the case of Vitamin C tablets and 30 percent in Sulphanilamide tablets. The variation was more than 50 percent for the rest. It was about 100 percent for 11 formulations and around 1,000 percent for 2 (Phenylbutazone and Chlordiazepoxide tablets).

Earlier, the Tariff Commission Report of 1968 provided data on the actual selling prices of the different manufacturers for 39 single-ingredient and 30 multiple-ingredient formulations. These are based on 18 bulk drugs referred by the government to the Tariff Commission for examining their costs and recommending their fair selling prices. Only 16 formulations, however, are relevant here. (In the remaining cases, prices cannot be compared because, the active ingredients involved, the strength and or the packing are not the same for the different sellers). Here, too, while some TNCs have been found to charge a lower price, on the whole, in only one (Vitamin C) out of the 16 cases, they were observed to be the cheapest sources. In 2 other cases (INH and Vitamin B 12) for some (but not all) dosage forms and pack sizes the TNCs' prices were the lowest. For the remaining formulations, the minimum price of the TNC exceeded that of the IS, the extent ranging from 8 percent to 385 percent.

### PRICE COMPARISON IN 1978

We now deal here with prices in later period for a larger sample of formulations. We have selected the 12 largest TNCs, accounting for 58.3 percent of the total sales of the TNCs in 1977 and 1978. Each of their products, however, does not appear to be relevant for price comparison. Under the Drugs (Prices Control) Order, 1970 (DPCO, 1970, which remained in force till DPCO, 1979 was issued) the manufacturers which opted for the alternative scheme of pricing (as most of the firms did) were officially permitted to have mark-ups even more than 150 percent for some products in exchange for mark-ups lower than 75 percent in others. Naturally, as the Hathi Committee noted, the manufacturers agreed to reduce the prices of those products which were relatively unimportant from the point of view of their sales. Out of the 648 products sold by the 12 TNCs, we

concentrate on 239 products, each of which accounted for more than 1 percent of the total sales of the firms concerned in 1978. The sample contributes around 90 percent of the sales for each of the firms.

The IS sold products identical (ie, containing the same active ingredients in the same dosage form) to those of the TNCs in 43 out of the 239 cases. But the same drug is often sold in different strength (eg. Ascorbic acid tablets, 100 or 500 mg). Such formulations are obviously sold at different prices. Considering each of these as a separate product, the total number of products considered goes up to 54 (Table 16). It may be noted that in 48 of these cases more than one firm belonging to the IS supplied the product.

As Table 16 shows, regarding Bisacodyl, 5 mg, Diethylcarbamazine, 50 mg, Mathergometrine Maleate, 0.125 mg and 9 other products comprising about 22 percent of the total of 54 products, the price of the TNC exceeded the minimum price of the IS, thus making purchase from any firm belonging to the IS cheaper. The TNCs' prices were between the maximum and the minimum prices of the IS in 38 products, or about 70 percent sold in different strength (eg. Ascorbic acid nicol, 250 mg. Metronidazole, 200 mg, Oxytetracycline, Hcl, 250 mg. Quiniodochlor 0.25 gm, etc. In other words, in each of these cases some indigenous firms charged a higher price. If an indigenous firm were chosen at random rather than the TNC, the purchase would not have necessarily been cheaper. But if one shopped around, then the cheapest source would invariably have been an indigenous firm for all the 38 products. In the remaining four products of Chloramphenicol Streptomycin Sulphate (suspension), Glybenclamide, 5 mg, Testosterone Propionate 50 mg, and Insulin Protamine Zinc, constituting only about 7 percent of the cases, all the indigenous firms charged a price higher than that of the TNCs. In other words, in 50, ie, 93 percent of the total number of 54 products considered for price comparison, the drugs were available from the IS at prices lower than those charged by the TNCs.

It may also be interesting to discuss the extent to which purchases from the TNCs were costlier compared to the cheapest source in the IS. While a TNC's brand of Betamethasone, 0.5 mg cost Rs.29.28 per 100 tablets, the same was available from an indigenous firm at Rs.2.05 — a variation of 1,328.3 percent. Similarly, in the case of Ascorbic acid 500 mg. and Hydrochlorthiazide 25 mg tablets, the price variation exceeded 600 percent and 500 percent respectively.

These, it may be argued, are exceptions. But wide price difference is not at all uncommon. In 22 out of the 54 products, eg. Analgin, 0.5 gm. Acetazolamide, 250 mg, Chloroquin Sulphate, 200 mg, Sulphadiazine, 0.5 gm Tolbutamide, 0.5 gm etc. the prices of the TNCs compared to those of some indigenous firms were observed to be double or more. The difference is more than 34 times in Chlorpropamide 100 mg, Metronidazole, 200 mg. Progesterone, 25 mg, and 8 others. The gap is less than 50 percent in only 12 cases (Table 16)

The total sales of the TNCs of the 54 products amounted to Rs. 285.1 million in 1978. If the same quantities of these drugs were purchased by the consumers from the cheapest source within the IS, then the expenditure would have amounted to Rs. 174.2 million. This shows that the purchases from the TNCs were actually costlier. The excess expenditure of Rs. 110.9 million as a percent of the minimum expenditure of Rs. 174.2 million, ie, 63.6 percent, may be interpreted as the extent to which the prices of the TNCs exceeded those of the IS in the aggregate, ie, for all the 54 products combined.

It may be briefly added here that the latest drug price policy as incorporated in the Drugs (Prices Control) Order, 1979 has failed to eliminate the price differences. Let us compare the nature of the price differences in 1978 with those in 1982. We have tried to find the price difference for each of the 54 products sold by the same TNC and the same indigenous firms, which charged the lowest price within the IS in 1978. Where information for such an indigenous firm were not available for 1982, we have chosen the next indigenous firm (in terms of prices in 1978) in order to ensure that the same indigenous firm is considered for comparison of price difference over time for a particular product. Price data were available for the same TNCs and the same indigenous firm for both 1978 and 1982 for 45 products. The prices of the TNCs were lower than those of the indigenous firms in 7 of these products in 1982 compared to 6 in 1978 (Table 17). The same table also shows that the extent of price differences in 1982 remained as wide as in 1978.

### Conclusion

The IS had technology to produce at least 76.8 percent of the value of the bulk drugs produced by the TNCs in India during 1976/76-77 and 1977/77-78 and at least 97.5 percent of the value of formulations sold by the TNCs during 1977 and 1978. The

implication is that technology will not be bottleneck for undertaking the task of replacing most of the manufacturing activities of the TNCs. But there may be other constraints, financial, entrepreneurial, etc. Given the present structure of the economy and the polity, the government may not also be able or willing to impose serious restrictions on the TNCs. Even if it does so, the TNCs may react by withdrawing from India. What are the costs, if any, of being deprived of the use of the drugs for which technology is not available with the IS or of making alternative arrangements for supplying them (eg. by imports)? It is necessary to analyse all these aspects also before we can arrive at any firm conclusion regarding the question of replacing the TNCs by the IS.

Our criteria and the nature of data used under-estimate the technological capability of the IS. If proper and more comprehensive data were available, then the estimate of the proportion of the output of the TNCs for which technology is available with the IS could have been higher. It is significant to note here that the drugs for which manufacturing technology is not available with the IS are not necessarily more difficult to make. Again, all the drugs for which such technology is not available may not be indispensably required. It may be useful to prepare in collaboration with health experts (doctors, pharmacologists, etc.), a list of drugs which are either unsafe, or ineffective, or for which cheaper substitutes are available, etc, in India and hence are not required.

In the context of our discussion of the manufacturing technology available with the IS, we have also raised the questions of quality, bio-availability and efficiency. In these respects there is scope for supplementing our analysis, which we on our part could not undertake because of the lack of access to relevant data at present. We have argued that since the TNCs utilise products manufactured by the IS, it may not be possible for the former also to ensure proper quality, if the latter is incapable of doing so. It is, however, important to compare directly the quality of the drugs manufactured by the two sectors. It may be added here that if some indigenous firms sell sub-standard drugs as is often alleged, then the option may not necessarily be to rely more on the products of the TNCs, but may actually be to take suitable action to prevent the sale of sub-standard drugs by these indigenous firms. Regarding the other two questions, on the basis of very small samples, for which data

were available, we have shown that the IS is capable for manufacturing drugs which are bio-equivalent to those manufactured by the TNCs and also can manufacture drugs more efficiently (in terms of cost of production) than the TNCs. Hence, we have argued that unless the converse is proved, the IS, in general, need not be considered as less efficient or incapable of producing drugs of proper bio-availability in view, however, of the importance attached to these question, there is a need to extend our analysis and find out what the situation really is in general. On the question of efficiency, we have shown that the TNCs may not produce drugs at the lowest cost at which they are capable of doing, because of their practice of over-pricing the imported materials. But even if the TNCs in general are found to be more efficient, the benefits of such efficiency, in any case, are not passed on to the users of the drugs since they, in general, charge higher prices than what the IS does. In such a case, it is difficult to question, on grounds of efficiency, the replacement of the TNCs by the IS. As regards bio-availability, several studies abroad have indicated that the problem is not important for all the drugs. Still, in specific context of India, it is worth while to analyse the differences in bio-availability for a larger sample of products manufactured by the TNCs and the IS.

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# Essential Vs. Irrational Drugs

T. Sundararaman

## Introduction

The fight against the gross inadequacies of the present health system in general, and the profiteering of the drug companies in particular is now increasingly getting focussed around one issue - that of essential drugs. That is, the demand for the production and adequate supply of some 200 to 300 drugs (indigenously as far as possible) and the banning of all others. This demand is not just a negative demand of banning certain drugs or criticising certain policies - but it also offers a concrete alternative. To quote Charles Malawar, "The benefits of a huge drug list are essentially to do with trade not health. The advantages of a restricted drug list include having fewer bad drugs and a reduction in drug-induced disease, and better information about drug use and less confusion about which drugs to use."<sup>1</sup>

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Estimates of inessential or harmful drugs on the market vary from 75 to 90%, the percentage being much higher in Third World countries. In UK 1 to 5 out of 4500 preparations listed in BNF<sup>2</sup> and in USA 8 out of 25 most frequently prescribed in 1976 were considered of questionable value. In India the estimated number of brand names in the market vary from 20,000 to 30,000 — one of the largest in the world.<sup>1,2</sup> The percentage of inessential drugs is about 90%. The problem is further compounded by the sobering knowledge that one in 5 drugs in the market are substandard if not down right spurious!

Despite the prevalence of this social disease in holoendemic proportions the medical community at large remains unaware of the essential drug concept or its rationale. It is 8 years now since WHO made its official recommendations (WHO technical Report Series No. 615) and a number of countries in the world. Mozambique, Bangladesh, Zimbabwe and now recently Mexico and Norway have already implemented these policies in varying degrees. In India itself a number of model essential lists have been drawn up starting with renowned, long buried Hathi Committee report, the PGI list and the Pune Workshop on essential drugs list. Yet hardly any textbook on Pharmacology or any of the other subjects mentions it. It is not included anywhere in the medical curriculum and in a recent series of Pharmacology workshops that included discussions on syllabus it was not even discussed.

### **Specific criteria for exclusion of drug**

To get a glimpse of the magnitude of the problem faced in India I will briefly review the extent of the Indian problem using the criteria applied in Bangladesh under the provision of the Bangladesh Drug Ordinance of 12 June 1982<sup>3</sup>.

To give concrete examples of the situation today we have chosen the October 1985 issue of Monthly Index of Medical Specialities (MIMS). This along with CIMS is the most commonly used reference book by practitioners. But I must stress that it only represents the tip of the iceberg. It has only 1697 brand names out of an estimated 30,000 brand names available in India. The most obnoxious and downright criminal drugs are largely, though not entirely, eliminated. Only the most popular and frequently prescribed are retained. For example, out of 46 available combinations of chloramphenicol and streptomycin on the market MIMS lists only 6; only 19 analgin containing drugs compared to 146

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on the market; 3 liquid preparation of tetracycline as compared to 16 on the market.

This paper confines itself to the MIMS issue only because of our inability to analyze the complete list of drugs - an urgent task. The figures I present should be multiplied by a large multiplier number to sense the real extent of the problem.

1. Prohibition on (a) antibiotics in combination with other antibiotics, corticosteroids or other active substance and (b) liquid (paediatric) formulations of antibiotics harmful to children (eg. tetracycline) <sup>3</sup>..... There are full 97 such unacceptable preparations listed in MIMS though only 13 in the section on antibiotics<sup>4</sup>. The rest come in eye and ear drops and antidiarrheals.

By far the worst offences are under the section in antidiarrheals. Diarrhoeas, the most common diseases in the country and its bigger killer in the third world. Most diarrhoeas are self limiting, ie, they cure by themselves, only oral rehydration being needed for support. Most are viral that do not respond to antibiotics. But obviously the drug industry will not allow such a big market to go by. Every conceivable combination has been tried. According to a MFC study published by KSSP, only 7 out of 47 preparations listed in MIMS (October 1984) are suitable for use.<sup>5</sup>

Chloramphenicol and streptomycin combination is one such example. Chloramphenicol is a dangerous drug meant for use only in typhoid and related infection and perhaps in very serious infections like meningitis. Streptomycin must be restricted only to tuberculosis to prevent the emergence of streptomycin resistant tuberculous strains. Anyway it is gross overkill. Together two unwanted drugs do not make a wanted drug. Yet MIMS lists 6 of these drugs. It lists 14 formulations containing streptomycin.

Then again drugs that interfere with movement must not be combined with antibiotics in fixed-drug combinations, especially for children as they are not to be used in infective diarrheas. We find this rule flouted by as many as 16 entries.

Now that ORT has received due publicity, the drug companies, partly with WHO backing, have moved into this field also. They add special flavours, special packing or some useless additional minerals and sell these packets under brand names at exorbitant prices. Tetracyclines syrups were banned in India by a gazette notification on 23rd July 1982. Yet Pfizer's Terramycin syrup and two

doxycycline syrups (doxycycline is only a long acting tetracycline) are entered in the latest issue of MIMS.

Then there are curious combinations like Sand cycline which combines tetracycline with two obscure drugs brox guinoline and brobenzoxaldine Indications given gastrointestinal disease!

In eye and ear drops the combination of corticosteroid and antibiotics are liberally used 23 for eye and 15 for ear - the majority in this section. Of course, MIMS mention that "steroids are not to be used in fungal, viral and tuberculous infections, infections not controlled by appropriate chemotherapy and in glaucoma" which would cover a majority of cases. Only definitely controlled bacterial infections can be given this combination but the potential for misuse is obvious.

Please note that all the examples mentioned above are of harmful, not just inessential drugs. I am convinced that criminal cases can be launched against some of these at least.

2. Prohibition on combinations of analgesics (there is no therapeutic advantage, it only increases toxicity especially in the case of kidney damage). Prohibition also on combinations of analgesics with iron, alcohol or vitamins.

Out of 59 preparations in MIMS analyzed in the MFC study, only 14 are justifiable. Addictive combination with tranquilizers are also frequent. One must also remember that many if not most of these are sold over the counter and the gross overuse of this category of drugs is compounded by the irrationality of the formulations. Often drugs are added in totally inadequate doses in fixed drug combinations or combined with vitamins or sedatives. Drugs like analgin which are banned abroad are dumped in our country on an enormous scale. 162 products with analgin are available on the market. Not only has analgin been proven to cause agranulocytosis but much cheaper, more or at least equally efficacious and much safer substitutes like aspirin and paracetamol are available.

3. The use of Codeine in any combination form is not allowed as it causes addiction. MIMS lists 13 such drugs and no preparation of Codeine is available separately.

4. Combinations of all types are prohibited with some exceptions that include some eye, skin, respiratory and haemorrhoidal preparations, co-trimoxazole, oral rehydration salt, antimalarials, iron-folic acid combinations and certain B-complex vitamins.

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Suffice it to say that the vast majority of drugs listed in MIMS would fall under this category. There are also numerous example of drugs where all the constituents are useless. Put together they make even less sense, especially in cough mixtures, which is dealt with later.

There are others like Pasumer Strong by Merck which is a combination of methyl testosterone, a dangerous hormone used without care, racephedrine which is contraindicated in many subgroups of patients like hypertension and Vit E and caffeine which have no therapeutic value. Together they are recommended by MIMS for functional impotence, which translated for the layman means impotence due to psychiatric/emotional causes and male hypogonadism. In practice, Merck promotes this drug for any male with any sexual problem and in our society there is an overabundance of this. 99% of them as any well informed person will know is due to psychiatric causes. Giving hormones and ephedrine, which has a psychostimulant (euphoria) side effect as a placebo is indeed criminal. Yet Pasumer Strong is one of Merck's profitable products.

5. There is a prohibition on vitamins in combination with other vitamins or any other ingredient (eg. minerals). An exception is made for B complex vitamins, other than Vitamin B<sub>12</sub>, which may be combined in a single product. Vitamin B<sub>12</sub> is acceptable only as a single ingredient injectable product. Liquid vitamin formulations are prohibited, except when supplied for babies in small bottles (upto 15 ml) with a dropper. Other liquid vitamins are prohibited because of wastage of financial resources and the tremendous misuse involved.

Now there is a major medical reason for this stricture on Vitamin B<sub>12</sub>. Vitamin B<sub>12</sub> dietary deficiency is very rare as its daily requirement is very low in the order of a few micrograms. However, when due to malabsorption or other rare causes B<sub>12</sub> deficiency does occur, its detection will be hampered by giving other vitamins or subtherapeutic doses of Vit. B<sub>12</sub> which will lead to a crippling neurological disorder. MIMS lists 162 drugs in its October 1985 issue, not a single one of them separately. The single largest group of products listed in MIMS is vitamins especially as tonics.

6. No cough mixtures, throat lozenges, gripe water, alkalis etc. will be allowed to be manufactured or imported as these are of little or no therapeutic value and amount to great wastage of our meagre resources.

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MIMS lists 70 such preparations. Some of the most ridiculous combinations and unheard of chemicals are used in these. Take for example Merind's VITMOL compound. Its constituents read as follows: Malt extract 1.870 gm, wild cherry fluid ext 0.5 ml, protein derived from bacteriological yeast 72 mg glycyrrhiza fluid extract 0.25 ml, quiacol 63 mg, pot. creosote sulfonate 0.22 gm, calcium hypophosphate 0.1 mg, potassium hypophosphate 50 mg, sodium hypophosphate 50 mg, ferric hypophosphate 6.25 mg, strychnine (which is specifically banned in India in tonics) 0.26 mg, and alcohol 9% v/v 1.3 ml per 15 ml. The only compound in this mixture which may have some value is the alcohol. And this is a highly priced, highly selling mixture.

7. The sale of tonics, enzyme preparation and restorative is prohibited. With the inception of pancreatin and lactase (which are permitted as single ingredient preparations) such products are said to have no therapeutic value and sometimes to be habit forming.<sup>3</sup>

Listed under tonics in MIMS are 45 preparations, under enzyme preparation, and 32 mineral and nutritional additives and 54 (mostly useless) and scattered under various headings like vitamins, anabolic steroids, food products and many more such useless products that we could well do without.

8. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed<sup>3</sup>.

9. This provision generally restricts products of marginal or uncertain therapeutic value and also harmful products subject to misuse<sup>3</sup>.

Under this heading comes the anabolic steroids against which KSSP has led a successful campaign in Kerala. The only disease which they can definitely be allowed is aplastic anemia. Even here there is a lot of controversy and current opinion is against using. Ironically a plastic anemia is most commonly caused by drug abuse. In practice anabolic steroids is almost always misused and being a dangerous drug known to result in a wide variety of side effects including hepatic carcinoma clearly ought to be restricted. Another example is Vit. E which has no known therapeutic value. 28 products are listed.

10. This provision prohibits the sale of prescription preparations

which are not included in current editions of either the British Pharmacopeia or the British Pharmaceutical codex.

11. Certain drugs, in spite of known serious side-effects and possibility of misuse, having favourable risk-benefit ratio, may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

This provision, though difficult to implement, points to the problems with certain drugs like gentamycin. There is no denying that gentamycin is a valuable drug especially against organisms like pseudomina. Yet it is liberally used by practitioners for trivial infections like diar often as a first line drug leading to a bumper of renal complication and drug resistant strains of pseudoman.

12 to 16: These criteria are economic criteria 12. This provision says that drugs may not be imported into Bangladesh if adequate quantities of identical or similar drugs are produced in the country.<sup>3</sup>

13. Basically the same provision (as 12) applies to the importation of raw materials for pharmaceutical products.

14. The role of the multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie solely with national companies, leaving the multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller national companies. Multinationals will, however, be allowed to produce injectable vitamins as single ingredient products.

15. No foreign brands will be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available/manufactured in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

16. No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis<sup>3</sup>.

Many papers have dealt with the economic aspects of the demand for essential drugs, the savings in national resources that will be generated by such measures and the exorbitant profits and ways by which multinationals generate them in India. I do not deal with

them, though as a doctor I would like to make a few observations.

The medical profession and its teachers have always avoided the discussion of costs. "Cost should not matter in the choice of treatment" has been the convenient and apparently laudable motive. But in practice it has meant that considerations of cost are left solely to a profit oriented drug industry. In all other commodities on the market the user compares the worth of the commodity purchased with its price. Here the patient, the user, buys in good faith whatever the drug prescribed to him. And the doctor who has prescribed as usually no idea of costs and prescribes according to a variety of pressures especially from the drug industry, however he may deny it.

If this is the attitude to the cost of a drug prescribed to an individual patient, the attitude is much worse towards questions of national resources, multinational profits, etc. Indeed we frown on discussing such mundane things as economics—"that's only for politicians" attitude. Economists here may not understand but I am sure that doctors working in the ivory towers of medical science, its teaching and research institution will agree.

There are other reasons why the medical community oppose these recommendations. I pose below some of these questions and the answers to the same.

Q.1. There are so many spurious drugs on the market and so many cottage industries produce substandard drugs. Isn't the brand name of a reputed drug a guarantee of better quality?

A. Indeed there are unacceptably high amount of spurious drugs and substandard ones. But the answer to this is better quality control. The machinery for this is woefully inadequate and must be strengthened.

If there are only 240 drugs on the market it is feasible to establish centres to regularly check and assess these drugs. But with tens of thousands, it is impossible. Some drugs like aminoridine sulfate (in Gabbromycin) or Thomzylamine in nasal drops, diodid (in cardiool) or attplugite (in Wyeths steptomazma) are almost unheard of. Is it possible to verify their effectiveness?

Then again studies have shown that the difference in bio-availability, in the few studies that have been done, are not much different and not always is the reputed firm's drug better.

Q 2. One knows that there are wide differences of opinions on drugs among experts. How is it fair to ban all these drugs and thereby

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deny the doctor the right to choose from the entire range? This limits the 'clinical freedom' of the doctor.

A. True, there are differences, but this has been shown in various studies to be limited to 15% of the drugs only. On 85% of all drugs there is agreement.

Secondly, any doctor remembers and write prescriptions from only a range of 50 to 200 brand-names. This particular list is influenced by the drug companies through its representatives. No comparative data on bio-availability or efficacy is available. An essential drug list makes the choice limited to a number of drugs decided by medical experts after considering all available data.

Thirdly, doctors and dispenserries are less likely to be confused by brand names. This is especially important when a patient changes doctors. Potentially fatal confusion between names like clothalton (clonidine containing) and hythalton or daonil and diamox have happened in my own limited experience.

Q.3 Is not the patient denied the best possible drug? In the sense that though a particular combination is not useful for most, for a particular person at a particular time it is the best. So all of those drugs should be available as all could be best.

A. In practice this argument is unsound, Clearly, no one patient can expect to enjoy the benefits of maximised choice, since no one doctor can possibly take full advantage of that choice. It is not practically possible for doctors to be fully informed about the few scores of drugs they do prescribe, let alone be adequately informed about the few thousands of drugs they never prescribe at all?

Long prescription lists as resulting from so many inessential drugs on the market cause poorer patient compliance, often inessential drugs like tonics being given preference by the patient to an essential one like digoxin.

Q.4. When the medical facts alone are so unambiguous why is the position on the essential list not accepted by the medical profession?

A.4. Organized opposition in India is little. Instead, apathy has been the weapon.

The Hathi Committee recommendations were not attacked, they were ignored.

The medical profession is surprisingly largely unaware of this issue. This concept needs active promotion. It has to be marketed. WHO's action programme on Essential Drugs has a budgetary

allocation of under 5 million dollars a year-less than would normally be spent on promoting one successful new drug.

The advantages of each essential drug for a given indication over all the others available in the market has to be spelled out. Detailed material in their use and superiority has to be highlighted within the profession even while we point out the reasons for deletion of the rest. The essential drug list and its rationale must be made a compulsory part of the medical curriculum.

The medical profession gains monetarily from the drug-dependency of the population. The tonics, vitamins, restoratives and injections that the public demands are an artificially created demand in which the medical profession cannot be excused. Generic prescription will reduce the mysticism that surrounds a doctors prescription and while it will mean better health, it will mean a more accountable doctor. Clearly, sections of the medical community will always remain opposed to these reforms for reasons that have nothing to do with Oath of Hippocrates.

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# **Essential Drugs and Public Policy**

**Dr. Naresh Banerjee**

## **Introduction**

The Report of the Committee on Drugs and Pharmaceutical Industry headed by Jaisukhlal Hathi was published in April 1975. The report (a) enquired at depth into the progress made by the "Drug Industry" in India and the status achieved, (b) recommended measures necessary for the public sector to attain leadership role in the manufacture of basic drugs and formulations, and in research and development, (c) recommended measures for promoting rapid growth of drug industry, in small and medium sector, (d) suggested ways and means for regional dispersal of the industry, (e) recommended the development and inflow of new technology for self-sufficiency in drug industry, (f) recommended measures for effective quality control and to assist the small sector units, (g)

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recommended measures for reducing drug prices and measures for rationalisation of the basic drug prices, (h) recommended measures to provide essential drugs to those who live in rural areas, who are poor, through an effective distribution system.

The subject of the seminar is very vital in the background of Health for all by 2000 A.D., as essential drugs are weapons in the hands of doctors and other health workers to fight against diseases; it is also a very pertinent and timely issue as the 7th five year plan of the Government of India is going to be finalised very soon. Positive deliberations of this seminar, I hope, shall be incorporated in the final draft as amendment by the working group concerning drug and pharmaceutical production for the 7th five year plan to do some justice to the Hathi Committee recommendations, to safeguard the interest of our nation and health care of the people of our country.

At present hardly 30% of our people who live in or near urban areas have got some access to treatment with modern drugs. But 70% of our people, mostly below or bordering poverty line who live mainly in rural areas and urban slums have got no or only marginal access to modern drugs, though they are the major victims of various diseases, both endemic and epidemic.

In the sphere of drug production and distribution, non-essential drugs and marginal remedies occupy on an average 65 to 70% of the total drug production in our country, including imports. The Essential Drugs with which 85% of the diseases commonly prevalent in our country could be prevented or treated have got low priority.

"Drugs for the people" is an essential part of "health for the people", which is inseparably integrated with the national health policy of our country, and is dependent basically on the socio-economic development to ensure food, portable water supply, viable employment, housing, proper disposal of waste, environment sanitation, education, etc. for the people.

A proper implementation of such a policy is mainly or entirely dependent on the determined people oriented political will of the Government of India, with setting up of suitable infrastructure, enforcing radical reforms in agriculture and industrial relation, eliminating other limiting factors, seeking cooperation of the State Governments, local bodies and motivated involvement of the medical and pharmaceutical profession and the community.

To ensure implementation of a people oriented drug policy with

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time bound programme in keeping with "Health for all by 2000 A.D", adequate allocation of funds, deployment of suitable technology along with social motivation of the people involved in management, production, research, distribution, dispensing and prescription of drugs are most vital.

### **Policy of the Government of India in the sphere of Drugs**

The Government of India did set up several committees for formulating a drug policy for our country. Of these committees, the Hathi Committee, 1975, clearly enunciated many positive guidelines in keeping with the morbidity pattern of our country, to ensure essential drug supply, through self-sufficiency in essential drug production, so as to cover wider sections of our people. But the Government of India picked up some marginal recommendations in piecemeal, succumbed to the pressure of multinational and big national drug lobby, and most of the positive recommendations have been kept in the cold storage. Mr. Bahuguna took only a few positive steps as per D.P.C.O. (Drug Price Control Order) 1978, and of late these have been reversed.

The Government of India has made the following drug policy statement during the 6th five year plan 1980-85.

- i) Development of self-reliance in Drug Technology.
- ii) Providing leadership role to the public sector.
- iii) Making drugs available at reasonable prices and in abundance to meet the health needs of the people.
- iv) Fostering and encouraging the growth of Indian sector.

(Refer page 267, 6th five year plan, Government of India, item 16.53).

The Government of India appointed in 1978 a working group for 6th plan which suggested investment of a small sum of Rs.400 crores only during entire plan period in drug industry and out of this allotted Rs.150 crores under public sector and Rs.250 crores under private sector, in the background of total allocation of funds for the 6th plan of Rs.97,500 crores (original estimate) and the revised allocation of Rs.1,56,000 crores (statement of the Planning Minister, N.D. Tiwari - ref. "Statesman" dated 8-12-80). This is inspite of commitment of the Government of India to ensure "Health for all by 2000 A.D."

The National Health Policy Document of the Government of India states (page-3, art-5): "India is committed to attainment of

'Health for all by the year 2000 A.D.' through the universal provision of comprehensive primary health care service...."

It is necessary to secure complete integration of plans for health and human development with the overall national socioeconomic development programme, specially in the more closely health related sectors, eg. drugs and pharmaceuticals, agriculture and food production, rural development, education and social welfare, housing, water supply and sanitation, prevention of food adulteration, maintenance of prescribed standards in the manufacture and sale of drugs and conservation of environment...."

Under "Medical Industry" (item No. 15), it is further stated that "The country has built up sound technological and manufacturing capability in the field of drugs, vaccines, bio-medical equipments, etc. The available knowhow requires to be adequately exploited to increase the production of essential and life saving (E.L.S) drugs and vaccines of proven quality to fully meet the national requirements, specially in regard to the national programmes to combat Malaria, T.B, Leprosy, Blindness, Diarrhoeal diseases etc. The production of E.L.S. drugs under their generic names, adoption of economical packaging practices would considerably reduce the unit cost of medicines, bringing them within the reach of the poorer sections of society, besides significantly reducing the expenditures being incurred by the governmental organisations on the purchase of drugs. In view of the low cost of indigenous and herbal medicines, organised efforts may be launched to establish herbal gardens, producing drugs of certified quality and making them easily available. The practitioners of modern medical system rely heavily on diagnostic aids involving extensive use of costly, sophisticated bio-medical equipments. Effective mechanism should be established to identify essential equipments required for extensive use and to promote and enlarge their indigenous manufacture for such devices being readily available, at reasonable prices, for use at the health care centers."

### **Drug Policy Recommendations of W.H.O. for Developing Countries (1983).**

"Drug policy has to be evolved in terms of health policy which in turn must be based on well defined national objectives for catering more effectively to the needs of the under-privileged and under-served. Drug policies have therefore to be formulated in the context

of health policy of the country.”

“The main objectives of a national drug policy should be to ensure drug supply for fulfilment of “Health for all by 2000 A.D” which must be to make available to the whole population the most effective and safe drugs of established quality at economic price.”

It is highly relevant for the developing world that drug policies should take into account not just the technological and scientific aspect of drug but the economic and social aspects also. In India, the drug policies are directly linked up with industrial and trade development, and highly influenced by these sectors, rather than by health considerations, where profit priority supersedes health priority.

The concept of Essential Drugs aims at fixation of priority for satisfying the health needs of the vast majority of population, with which more than 80% to 90% of the common diseases, could be dealt with instead of high priced sophisticated drugs for a small segment of population. Essential drugs may not meet the health needs of every person of every disease. .

W.H.O. has suggested an essential drug list, for the different levels of health care delivery:

- i) A small essential drug list may contain only a few safe medicaments for immediate relief of common symptoms and complaints and prophylactic medicines and vaccines, which can be served by the peripheral level health workers and paramedicals without any risk involved (26 drugs).
- ii) The essential drug list for treatment of common diseases prevalent in the community and where clinical diagnosis is possible (96 drugs).
- iii) The essential drug list should be further enlarged for District and teaching hospitals with various specialist departments, where more sophisticated investigation and treatment are possible (200 drugs).
- iv) This drug list should be extended further with inclusion of about 240 drugs for the super speciality departments. The West Bengal Government has adopted these guidelines.

The following are the W.H.O. guidelines for Essential Drugs:

- i) Countries should adopt its essential drug list depending on health needs, i.e., best drugs to meet the health needs under defined local conditions.

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- ii) Serving preventive and curative purpose at different levels of health services.
- iii) Proven efficacy, safety, quality, favourable pharmacokinetic properties.
- iv) Drug needs not Drug demands.
- v) Drugs for widest possible coverage rather than individual needs of the few.
- vi) Cost to represent the major selection criteria.
- vii) Single drug rather than combinations, unless efficacy of combination is scientifically proved.
- viii) Impact on drug industry to give priority to production of essential drugs or their procurement.
- ix) International non-proprietary names rather than "brand names".
- x) Cost benefit - risk ratio.
- xi) Raw materials, intermediates and solvents for essential drugs should be manufactured locally under approved facilities.
- xii) Most of the people who are still outside the ambit of health care system depends on traditional medicine for relief. These remedies should be cheap, easily available, relatively non-toxic and efficacious. Those traditionally used and found effective may be adopted in the primary health care programme, after scientific evaluation.

**Assessment of progress achieved during the 6th five year plan**

The production target for bulk drugs and formulations at the end year of the 6th Five Year Plan (1984-85) was estimated at Rs.815 crores and Rs.2450 crores, respectively. The details are as follows:

Plan year	Production of Bulk Drugs (in crores)	Production of Formulation (in crores)	Out of Formulation Essential Drugs Production (in crores)
1980-81	255	1260	360
1981-82	289	1430	400
1982-83	325	1600	430
1983-84	345	1660	466
1984-85 (Projected)	405(815)	1840(2450)	520

These figures clearly reveal that the production target could not be fulfilled during the 6th five year plan. Bulk drug production was

less than 50%, and formulation production was to the tune of 75%. Government planners did not give any importance to Essential Drugs production so that it shows very marginal increase.

There are gross technological gaps in many items of formulations including Essential Drugs. Some items are imported in the name of raw materials almost in penultimate stage. Technological gap in the sphere of drug intermediates and solvents are enormous.

Providing leadership role to the public sector failed, as shown below

Sector wise production	Bulk Drug percentage	Formulation percentage	Total
Public Sector	26.4	13.5	39.9
Organised Sector	32.5	37.1	69.6
Foreign Sector	30.1	40.0	70.1
Small Sector	11.0	9.4	20.4

The figures referred to above clearly reveal that the public sector is not in leading position; it is only in the third position. This is due to the lop-sided planning with small allocation of Rs.150 crores in public sector and greater allocation of Rs.250 crores in private sector and also because Transnational sector, which is powerful enough prevail upon the Government and get accommodated their demands surrendering the priority objective.

Making drugs available at reasonable prices and in abundance to meet the health needs of the people also failed. The prices of essential drugs are going up day by day. Prices of most of the essential drugs have been escalated while those of only few have been reduced.

Anti TB Medicine	Packing	Prices in 1979	Prices in 1981	% increase
a. INH-PAS	100 gm. tin	14.45	24.00	67
b. INH (450 gm)	bottle	51.81	91.35	53
c. Streptomycin	0.75 gm	1.37	2.41	76

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d. Ethambutal	600 mg (10 tabs)	9.45	11.50	21.69
e. Pyrazinamide	10 tabs	6.35	15.30	141

Sharp rise in raw materials prices per Kg is as follows

Materials	From	To
Pyridin	Rs. 100/-	Rs. 140/-
Acetic Anhydrate	Rs. 12/-	Rs. 19/-
P.N.C.B.	Rs. 19/-	Rs. 30/-
Phenol	Rs. 19/-	Rs. 40/-
Methanol	Rs. 4/-	Rs. 11/-
Propylene Glycol	Rs. 18/-	Rs. 31/-
Glycerine	Rs. 30/-	Rs. 80/-
Acetic Acid	Rs. 8/-	Rs. 12.50

The I.D.M.A. has stated on 25th August, 1984, that "due to irrational Governemnt policy, imports of bulk drugs with 100% duty against the duty of 131% for drug intermediates has sharply raised the cost of bulk drugs manufacture in our country in comparison to the cost of imports."

There are acute shortages of the following drugs which are essetial and life saving. 1. Iodine Group (Eltroxin etc.). 2. Chloroquin, Primaquin, 3. Anti Leprosy Drugs (Dapsone/ Hansepran), 4. Vitamin 'A', 5. Anti TB Drugs - rifampicin, isoniazid, thiacetazone, streptomycin, ethambutal, 6. Paracetamol, Aspirin, 7. Chloramphenicol, 8. Trimethoprim, 9. Penicillin, 10. Anti-diabetic, 11. Psychotropic, 12. Anti-filaria, 13. Anti Hypertensive. The list does not exhaust.

The unplanned categorisation of drugs in 1978 (D.P.C.O.) has resulted in the shortage of some (E.L.C) drugs on the one hand and the higher prices on the other.

A multi national company has cut down, of example, the production of Dapsone from 38 tonnes to 17 tonnes and D.E.C. (anti-filaria) from 56 tonnes to 23 tonnes, whereas it increased the production of Trimethoprin Sulphamethaxazol to the tune of 200 times the production quota to earn huge profits.

In the case of some common drugs, the international prices are lower than those in India.

Some common drugs	Prices in India (per kg.)	International Prices (per kg.)
Doxycyclin	5,890/-	1,337/-
Ithambutal	620/-	320/-
Frusemide	1,426/-	450/-
Gentamycine	35,670/-	3,500/-
Vitamin (B 12)	494/-	132/-
Ampicillin	1,392/-	743/-

Why should we put the prices higher than international rate?

### **Fostering the growth of Indian sector**

The Government of India has allowed the following percentage of excess production.

- |                                   |               |
|-----------------------------------|---------------|
| i) Foreign Monopoly concerns      | More than 50% |
| ii) Public Sector                 | More than 40% |
| iii) Indian sector (non-Monopoly) | More than 30% |

Over and above this, due to the major control over the bulk drugs imported from their mother or sister concerns, the foreign monopoly concerns produce much in excess of their production quota mainly on profit oriented formulations having marginal or of no therapeutic values, at the cost of essential drugs. The above points have been raised in details to show that the Government's pious policy pronouncements in the 6th five year plan have been sabotage by its own implementation machinery, and unless these are checked and rectified "Drugs for Masses" could not be implemented.

### **Need based drug production**

The 7th Five Year Plan approach paper has suggested a rise in the demands of drugs at the end of year of 7th Five Year Plan.

- i) Bulk drugs—worth Rs. 1,062 crores.
- ii) Formulations—worth Rs. 3,885 crores.
- iii) Export of drugs will rise from Rs. 132 crores to Rs. 500 crores.

In formulating the drug production they have missed the basic aspect suggested by the Hathi Committee that it should be based on "need" not "demands" and that it should be based on the quantum of essential drugs needed to meet the morbidity pattern specifically

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mentioned in National Health Policy document and the W.H.O guidelines.

Mr. George Daniel, President O.P.P.I. has suggested: "Drugs needs of India will be to the tune of Rs. 16,000 crores by 2000 A.D." He further suggested that to make the drug prices reasonable, control on production of all sectors should be liberalised.

In suggesting this he has not mentioned about the priority and quantum of essential drugs production to tackle the morbidity pattern of our country. From the point of view of drug industrialists his suggestion to liberalise control on drug production of all sectors will eventually lead to gross exploitation of people in the name of health care, equating essential with non essential drugs, with a view to earn more profit with higher mark up.

The then Union Minister of Chemicals and Fertilizers, Mr. Vasant Sathe, have suggested the formation of a "National Drug Authority" to bring certain amount of discipline in industry which would be responsible for production and distribution of drugs, and to formulate code of conduct for the manufacturers and distributors. He emphasised the need for research and development and improved technology for increasing export and for meeting the growing need of essential drug within the country. The Government would give the industry all necessary incentives for production of high quality drugs at reasonable prices. These pious wishes and vague utterings cannot be fulfilled without fixation of priority and responsibility with time bound programme for implementation, sector and industry wise, with adequate deployment of fund and setting up of suitable infrastructure.

In spite of a steady increase in drug production, we find a gross shortage of many essential drugs to combat and prevent Malaria, Filaria, Tuberculosis, Diarrhoeal diseases, Tetanus, Whooping cough, Diphtheria, Night blindness, Polio, Rabies, Enteric fever, Leprosy, Giardia, Diabetes, Epilepsy, Anaemia, Goiter, Kalaazar, Encephalitis, Infective hepatitis etc. Some examples are cited below.

Items	Production (Present)	Import (Present)	Projected requirement (by 1990)	Estimated shortfall
1. Chloroquine (M.T.)	80.82	198.25	500	220.93

2. Amodiaquin (M.T.)	30.15	NIL	100	69.85
3. Primaquin (Kg)	NIL	100.00	400	300.00
4. Strepto- mycine (M.T.)	239.60	8.27	500	152.13
5. Aspirin (M.T)	1325.35	74.24	2000	600.41
6. I.N.H. (M.T.)	199.01	NIL	400	200.99
7. Dapsone (M.T.)	30.94	34.70	250	184.36
8. Penicillin (M.T.)	358.00	20.00	500	122.00
9. Vit. A	52.00	20.00	150	78.00

Without a proper authority to control deployment of fund, raw materials and technology along with industry-wise production quota allotment of essential and bulk drugs, and systematic performance monitoring, the social objective of "Drugs for Masses" would be a day dream. These should be the task of "National Drug Authority" with adequate powers to deal with delinquents in respect of quantity and price rigging.

#### **Adequate supply of essential life saving drugs.**

It is necessary to increase the allocation in Health budget to the tune of at least 10% of the national budget (during the 1st Five Year Plan health budget was 3.30%, whereas in the 6th Plan it came down to 1.87%), without which no progress could be achieved, as economic development of a country depends on the productivity outcome of healthy working force.

It is necessary to revise the allocation of 7th Five Year Plan for development of drug industry including R&D at least to the tune of Rs. 3,000 crores. (in place of Rs. 400 crores as was allotted during 6th plan). Sector wise allocation should be as follows:

- i) To ensure a leading role for the public sector, a sum of Rs. 1750 crores be allotted, for development of public sector units including R&D which was only Rs. 150 crores in the 6th Plan.
- ii) Private sector allocation of Rs. 500 crores (it was Rs. 250 crores)
- iii) Small sector allocation of Rs. 750 crores (employment oriented sector).

The public sector can take a leading role in production of bulk

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drugs and E.L.S. drugs with need based R&D applying latest technology and can offer technological help to small and medium sector.

Priority for production of E.L.S. drugs, including drugs for preventive care from 30% of the total production as at present to 60%, during the period of 7th five year plan.

- a) Production capacity of public sector units should be geared to 75% of the capacity for manufacturing bulk drugs, E.L.S. drugs and intermediates.
- b) National big-medium and small sectors' production capacity should be geared to the tune of 60% of the capacity for E.L.S. Drugs.
- c) Foreign transnational sector production capacity should be increased to the tune of 50% of their production capacity, provided they agree to transfer technology and ready to dilute their equity share holding to the extent of 20% to 30%. Public financial institutions should have major share holding, as a preliminary step towards nationalisation.

All the E.L.S. drugs as advised by the Hathi Committee should be in "Generic Pharmacopeal names" instead of "Brand names". At least a sum of Rs. 250 crores have been spent by the industry last year to create "Brand Image" which are included in the price structure of drugs.

Drug Production should be 'quantum' based.

Due to the high rate of "inflation", "devaluation", "price hike", deficit financing", and "foreign loan" etc. fixation of production target in terms of rupee will lead to growing shortage in quantum of production, though it might show some progress in terms of rupee. Taking price index base line as Rs.

100 - in 1970, we find it has gone up to Rs. 360.12 - in October 1985.

To make self sufficiency in essential drugs the following steps should be adopted.

- a) Special incentive should be offered to those who are interested in production of bulk drugs to the extent of 50% of their production capacity.
- b) Unrestricted release of bulk drugs required for manufacture of essential drugs at import price or production cost.

- c) Strict vigilance should be maintained so that the bulk drugs released for essential drugs are not diverted for profit oriented branded products, tonics, pick-ups, marginal remedies, etc.
- d) List of E.L.S. drugs including drugs for preventive care should be revised, updated and be placed under one category, revising the D.P.C.O. 1978. A special expert committee should be set up for the purpose of review and report every 6 month annually.
- e) No bulk drugs or E.L.S. drugs shall be allowed to be exported till we are in a position to meet the 100% need of our people. But both the working group and the 7th five year plan documens have given greater importance for export promotion.
- f) The working group has suggested that R&D costs should be meet from the sale revenue. But I suggest 50% of the R&D costs should be met from plan fund and 50% from the sales revenue of the profit oriented marginal remedies.
- g) A special technological cell should be set up to develop self-sufficiency in the production of E.L.S. drugs including solvents and intermediates, relevant to the morbidity pattern of our country. Serious attempts should be made to harness phytochemical and petrochemical coal carbonisation and biological resources, including essential gases like oxygen, nitrous oxide etc, alongwith development of self-sufficiency in diagnostic, therapeutic, preventive, promotive, bio-medical and surgical instrument and accessories including laboratory equipments. To harness biological remedies like insulin, thyroid, ovarian and testicular hormones, special scientific abattoir have to be set up préferably in the eastern region where meat eating population are the largest in number.

The following steps are suggested to reduce the drug price:

- a) There should be no sale tax, octroi, excise duty, surcharge on E.L.S. drugs in generic names. Government should subsidise generic drugs as and when required, and these drugs shall be placed under one category.
- b) E.L.S. drugs should be drawn out of the purview of commercial commodity list with no obligation for defence equipments production etc.
- c) All E.L.S. drugs should be in generic names without exception. But essential drug combinations in brand names shall not be

allowed.

- d) Import of bulk drugs or penultimates should be allowed till self-sufficiency is achieved with priority for production of E.L.S. drugs at international prices and of standard quality.
- e) Freight equalisation should be established throughout the country with regional disbursement of drug industry, as our country is vast with frequent disruption of communication and other constraints.
- f) Combinations of other drugs with E.L.S. drugs, should be avoided.
- g) Proper scientific packing should be introduced avoiding costly sophisticated packing.
- h) Fix up uniform price abolishing leader price. Mark up of E.L.S. shall not exceed 40% to 50% in case of 95 essential priority drugs. But the Government is contemplating to revise the mark up of E.L.S. drugs from 40% to 50% in cases of 28 priority drugs and their formulations out of the 96 essential priority drugs and the rest 68 drugs and their formulations will be allowed 100% mark up as recommended by the National Drugs and Pharmaceutical Council dominated or influenced by the organised sectors like O.P.P.I., I.D.M.A., etc. This will make the essential drugs more costly.

The following steps should be adopted to fulfil the objectives of "Drugs for All by 2000 A.D."

The population of India is now over 70 crores, by 2000 A.D. it will cross 100 crores. By investing Rs. 3,000 crores with high priority for essential drugs we shall be able to increase the drug coverage of our people from 30% to 55% by the end of the 7th plan. By investing Rs. 5000 crores and Rs. 7000 crores during the 8th and 9th plan respectively, we shall be able to cover the entire people of our country with essential drugs by producing Rs. 4000 crores worth of bulk drugs, 12,000 crores worth of Essential Drugs, and 6000 crores worth of formulations annually, provided inflation, price hike, deficit financing and foreign loan do not create resource constraints, and the present socio-economic set up with pressure from powerful industrial lobby do not stand in our way of fulfilment of our objectives, and world peace remain undisturbed.

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# **Public Sector and National Drug Policy**

**T. Ravindranath**

## **Introduction**

This topic is rather intriguing, because it is open to a variety of interpretations. As for example, it could signify the interrelationship between the public sector and the national drug policy or the role of the public sector in shaping the national drug policy or the impact of the national drug policy on the public sector. However, I chose to interpret the topic in a way to impart some futuristic connotations as well as to avoid traversing the beaten track of policy projections.

## **Drug Policy - Retrospect**

The Kerala Sastra Sahitya Parishad (KSSP) has commissioned indepth studies on the status and growth of Indian Drugs and Pharmaceutical industry as well as the role of multinationals in drug industry. The IDMA representing the indigenous sector and the OPPI representing the participative (foreign & Indian) sector have come out with reports and authoritative studies aimed towards influencing the evolution of a national drug policy. However, there is nothing truly "national" in scope or content in these policies, which are characterized more by adhocism than any deliberate formulation linked to the health care needs of the nation in the coming years.

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No purpose will be served by reiterating past policies which were essentially of a regulatory nature. The recommendations of the Hathi Committee which led to a certain categorisation of drug production and formulation on a sectoral basis are well known. This was followed in 1978 by new drug policy involving reservation of drugs production to public, private and open sectors as well as a tighter check on the foreign sector. We had a committee on high technology in 1979 which analysed the technological component of more than 200 drugs from the point of view of foreign equity dilution. The policies followed in the drugs and pharmaceutical sector have thus largely been concerned with sectoral regularisation, production control, price and distribution control and control on profiteering in the production of life saving drugs. Both in the formulation and implementation of these policies, most of us also know that considerable amount of lobbying was done by interested groups in the industry, but I am not sure of the magnitude of the role played by the public sector represented by only a few units in this context. Unlike other segments of the Indian chemical industry such as fertilizers or petrochemicals where the public sector enjoys commanding heights in production, turnover and growth so as to influence national policy formulation, the public sector engaged in the production of drugs and pharmaceuticals has probably only a tenuous relationship in respect of national policy formulation affecting the growth and product mix of this sector. Herein lies, therefore, a fertile scope for the public sector to play a more decisive role in national drug policy formulation oriented towards enhancement of per capita availability of life saving drugs and implementation of programmes for diversification ensuring technological self reliance in providing for the health care needs of Indians in the coming decades.

### **Health Care Scenario**

The Seventh Five Year Plan has made a provision of Rs. 6700 crores for health and family welfare. A large chunk of this outlay will ultimately find its way into the drug and pharmaceutical industry, despite the prevalence of other systems of medicines such as ayurveda, homoeopathy, unani and siddha in India; because almost 42% of the provision will be spent on primary health centres. Health care for all by 2000 AD in India is proposed to be met by proliferating these primary health centres, which will also stock allopathic

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medicines. The scientists, technologists and industrialists have to evolve health care strategies in the coming year taking into account the fact that India's population by 2000 AD may probably exceed 100 crores. More than 70% of Indians have no access to modern medicine produced by the drug industry. The growth of hospitals, dispensaries and primary health centres has been rather poor compared to the size of our rural population. India has over seven lakhs inhabited villages, but the total number of rural hospitals is only 1700 (1 hospital for 400 villages). Health care profile between the urban and rural sectors may also change because of rural migration to urban centres. Urban life is characterized by cardiovascular ailments, hypertension, diabetes, psychosomatic diseases, nutrition oriented disorders and occupational health hazards. Rural endemic and epidemic diseases pattern may not undergo any radical change, but the traditional health care systems will have to be considerably supplemented through preventive allopathic procedures.

### **Drug Industry—A Profile**

The Indian drug industry is composed of about 143 undertakings in the organised sector and the number of small scale units is estimated to be anywhere between 5000 to 8000. The production of bulk drugs during 1984-85 is valued at Rs. 374 crores and the value of formulated products at Rs. 1650 crores. By the end of the 7th Plan the value of formulations will rise to Rs. 2500 crores at current prices. A recent study of the Working Group of the Planning Commission states that the annual average investment in this sector to achieve the 7th Five Year Plan target should be between Rs. 100 and 150 crores. The National Council for Applied Economic Research has estimated the demand for drugs by 2000 AD at Rs. 16,000 crores. To meet this order of demand by 2000 AD, the industry has to aim at an annual growth rate of 15-20%.

The product mix of this sector comprises antibiotics, sulphas and related drugs, analgesics, anti-inflammatories, vitamins, steroids, anti-TB drugs, anti-malarials, anti-diabetics (oral), anti-leprotics, anti-amoebics, anthelmintics, diuretics, barbiturates, tranquilizers and hypnotics, antihistaminics, antihypertensives and cardiovasculars, anaesthetics, anti-convulsants, anti-depressants, anti-mitotics, anti-diarrhoeals, peptic ulcer and gastritis, synthetic vegetable drugs, animal products, calcium salts, iron salts, antacids

and sera, vaccines and toxoids. Most of these products are, however, manufactured using technologies, which are considered nearly obsolete in advanced countries. Older antibiotics such as chloramphenicol, doxycycline and erythromycin are even now made from penultimate intermediates and we have no plans for producing antibiotics such as pivampicillin, ticarcillin or later cephalosporins. Besides, several synthetic drugs are also made from penultimates. Production of even first generation cephalosporins or rifampicin is rather minimal and the current demand is largely met by imports. Table I shows the percapita availability and assumed projections for some selected groups of drugs. The conclusion is inevitable that even the projected availability will be far short of the requirements even if newer investments and capacities become feasible as planned.

### Health Care—Prospect

The World Health Organisation has identified six major diseases, of which five are specific to tropical countries such as India. These are malaria, leprosy, leishmaniasis, lymphatic and other filariasis and schistosomiasis. The number of cases of malaria in 1979 was about 3.1 million and even by 2000 AD the chances of its total eradication are not very bright. Along with the existing preventives and curatives, technologies for newer antimalarials such as liposome entrapped primaquine, mefloquine, and quinghasu (a biotherapeutic isolated from *Artemisia annua*) will have to be developed. Considerable amount of research is going on for the development of vaccines against malaria and leprosy and probably commercially feasible technologies may become available before the end of this decade. Leishmaniasis, locally known as *Kala Azar*, occurred in Bihar in an epidemic form in 1977-78 for which the known curatives are antimonial tartar emetic, sodium antimony gluconate, etc. Filariasis affects more than 250 million people in the tropics and the greatest number of patients are found in India. Diethylcarbamazine citrate is the drug of choice. The industry should consider innovative technology development and large scale production of this specific drug, because a large majority of our population in the coastal and other areas are prone to this parasitic infection. Schistosomiasis is predominantly an infection of rural and agricultural communities due to substandard hygienic practices and absence of adequate sanitary facilities. On a world wide basis, more than 200 million suffer from schistosomiasis and about 500 to 600

**Table I**  
**PER CAPITA AVAILABILITY OF DRUGS AND**  
**PHARMACEUTICALS**

Drug group	Estimated pro- duction 1983-84 (tonnes)	Per capita availability <sup>1</sup> 1983-84 (gm) AD	Per capita availability for Urban on 100%		Per capita availability <sup>3</sup> 1983-84		Per capita availability <sup>3</sup> 2000 AD	
			1983-84	2000 <sup>2</sup>	Urban	Rural	Urban	
1	2	3	4	5	6	7	8	9
Antibiotics	892.0	1.189	4.760	5.950	2.720	0.680	0.4198	
Sulphas							1199.0	1.599
Vitamins	1109.0	1.479	5.915	7.390	3.380	0.845	5.218	1.304
Analgesics & Antipyretics	2179.3	2.906	11.623	14.530	6.640	1.660	10.256	2.564
Cortico- steroids	2.6	0.0035	0.014	0.017	0.008	0.002	0.012	0.003
Anti-TB	504.0	0.672	2.688	3.360	1.536	0.384	2.372	0.592
Anti- malarials	153.0	0.204	0.816	1.020	0.468	0.177	0.720	0.180
Anti- dysentery	552.0	0.736	2.944	3.680	1.684	0.421	2.598	0.650
Anti- diabetics	47.0	0.0063	0.251	0.313	0.144	0.036	0.222	0.056
CNS- stimulants	18.0	0.024	0.096	0.120	0.056	0.014	0.084	0.021
Diuretics	9.0	0.012	0.048	0.060	0.028	0.007	0.042	0.010
Anti- Asthmatics	2.9	0.004	0.015	0.019	0.008	0.002	0.059	0.004
Cardio- vascular	25.1	0.033	0.134	0.167	0.076	0.019	0.112	0.030
Anaesthetics	66.0	0.088	0.352	0.440	0.201	0.050	0.310	0.078
Antihista- mines	25.0	0.033	0.133	0.167	0.076	0.019	0.112	0.030
Antihon- minics	14.0	0.019	0.075	0.093	0.044	0.011	0.066	0.016
Psychotropics	19.0	0.025	0.101	0.127	0.058	0.015	0.090	0.022
Antifilarials	29.0	0.039	0.155	0.193	0.088	0.022	0.136	0.034
Antileprotics	32.3	0.043	0.172	0.215	0.100	0.025	0.152	0.038
Immunologi- cal agents	0.007	0.000007	0.00004	0.00005	0.000005	0.000005	0.00003	0.000008
Antoba-								

Materials	62.0	0.083	0.331	0.413	0.189	0.047	0.292	0.072
Total								
production	6934.0	9.250	—	—	—	—	—	—
Total imports								
(1983-84)	4126.0	5.501	—	—	—	—	—	—
Total								
availability	11060.0	14.750	58.99	73.730	33.71	8.43	52.05	13.01

Notes: 1. 750 million population assumed.

2. 1000 million population assumed and total production assumed at double the level of 1983-84.

3. Urban-Rural population ratio assumed as 30:70 for 1983-84 as well as 2000 AD and per capita availability ratio 80:20.

millions are exposed to this infection. The drugs used to cure this infection are metrifphonate (bilarcil), oxamniquine (mansil/vansil) and praziquantel (biltricide) for which the drug industry should develop innovative technologies in collaboration with the research laboratories.

### Biotherapeutics

The international trends indicate that biotechnology will play a dominant role in the future development of the health care products. Several drug companies in USA have developed flourishing market for biodiagnostics, biotherapeutic, hormones and vaccines using recombinant DNA, hybridoma, DNA probes and other immunological techniques. Table II lists some of the recent developments of technologies, which are undergoing clinical trials in advanced countries.

Medicinal and veterinary pharmaceuticals have been produced using direct gene cloning, chemical synthesis of gene or by reverse transcription of copy DNA (cDNA) from messenger DNA (mDNA). Newer biotechnologies for the production of non-chemical antibiotics, antidiabetic agents (Humulin), cardiovascular compounds, antihypertensives may become commercially operational in international markets. Plant cell and tissue culture are gradually emerging as competitive techniques to produce biologically active chemicals and therapeutics under controlled conditions divorced from environmental constraints of the natural habitat. Plant tissue culture techniques have also been effectively used for the production of speciality chemicals. Recent developments in this are given in Table III.

Tissue culture is useful for rapid growth of medicinal plants in greater volume. Plant cell cultures typically produce lower yields of plant metabolites, but the facility of producing a larger volume of the substrate material can compensate for lower yields. Technologies

**Table II**  
Biotherapeutics via Genetic Engg. (rDNA technology)

Sl. No.	Biotherapeutics area	Specific disease/application	Stage of development
1.	Viral diseases using $\alpha$ - interferones and $\beta$ - interferons	Herpes genitalis Herpes labialis Hepatitis B Multiple sclerosis	Final clinical trials
2	Cancer using mixed interferons, $\alpha$ -interferons and $\gamma$ -interferons	Broad range of advanced cancer Melanomas Lymphomas Leukaemia Breast cancer Kidney cancer Ovarian cancer	Phase I and II clinical trials
3.	Regulatory Proteins:		
i)	Human growth regulators: Growth hormone Somatostatin	Growth promoter, healing of burns Adjunct to insulin	
ii)	Calcium regulators: Calcitonin Parathyroid hormone (PTH)	Bone disease therapy Osteoporosis therapy Calcium metabolism	
iii)	Reproductive hormones: Leutenssing hormone (LH) $\beta$ -chain	Antifertility	
iv)	Neuroactive peptides $\beta$ -Endorphin Enkephalin	Analgesia	Successful in Lab Under further development
v)	Lymphokines and immunoactive peptides interleukin-2	Immunotherapy	
vi)	Respiratory system regulators $\alpha$ -1-antitripsin	Emphysema	

using recombinant DNA, protoplast fusion, gene amplification, etc are becoming operational in the West, but considering the present research status in India in these fields, one cannot foresee any rapid development in indigenous expertise which can be commercially used by drug and pharmaceutical sector even by the end of 2000 AD

**Table III**

Biotherapeutics derived from plants through Plant Cell Tissue Culture

Product	Use	Source
Codeine	Analgesic	<i>Papaver somniferum</i>
Serpentine, Ajmalicine	Antileukaemic	<i>Catharanthus roseus</i>
Digoxin	Cardiotonic	<i>Digitalis lanata</i>
Quinine	Antimalarial	<i>Cinchona spp.</i>
Ginseng	Stimulant tonic	<i>Panax ginseng</i>
Reserpine	Antihypertensive etc.	<i>Rauwolfia serpentina</i>
Shikonin*	Antibacterial	<i>Lithospermum erythrorizon</i>
	Anti-inflammatory	
Verbascoside		<i>Syringa vulgaris</i>
Cinnamoyl Putrescines		<i>Nicotina tobacum</i>
Benzoylisoquinolines		<i>Berberis stolonifera</i>
		<i>Coptis japonica</i>
Nicotine	Anthelmintic	<i>Nicotina tobacum</i>
Rosmarinic acid		<i>Coleus Flamei</i>
Berberin	Antibacterial,	
	Antimalarial &	<i>Coptis japonica</i>
	Antipyretic	
Ubiquinone glutathione	Cardiovascular	<i>Nicotina tobacum</i>

## Conclusion

Reverting back to the topic "Public Sector and National Drug Policy", I wish to suggest that national policy formulation should be based on health care objectives and goals. While regulatory guidelines to maintain balanced sectoral development, elimination of profiteering, adoption of generic names in preference to brand names, fiscal and monetary incentives, patent protection, reasonable restriction on repatriation of earnings in foreign exchange and other measures may be desirable these cannot be a substitute for a national drug policy whose principal objective is to provide the nation with health care products in sufficient quantities. It is in this area that the

public sector has a vital role to play not only through expansion and diversification of capacity for the production of essential chemo and biotherapeutics, but also seek to achieve commanding heights in fostering technological self reliance in respect of modern therapeutics. The private sector, whether domestic, small scale or foreign, obviously cannot command the massive resources required to provide a need based self reliant health care system in the country. The choice is clear, but can the public sector take up the challenge?

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# **Essential Drugs and Public Policy**

**Dr. V.C. Mathew Roy**

Drugs form an important factor in the delivery of health care, curative, preventive, promotive and rehabilitative. These consists of ordinary drugs, essential drugs and emergency drugs based on the urgency of the need. So one has to take stock of the present list of drugs in vogue and re-classify them based on their indications for use. So long as there is a heterogenous system of medical care this classification is very difficult. Therefore a restructuring of health care may be required. To start with, this not an easy task. For example, what is the system of health care required for the country or state. Modern medicine, Homoeopathy, Ayurveda or Unani? Should there be a public policy limiting the use of drugs in general or in particular? If so, certain questions naturally arise. Drugs for what illness or for whom? How much of these drugs are required at a given time? Who will manufacture these drugs - private, public or both? Who will control quality, ethicality and supply.

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Dr. V.C. Mathew Roy, Professor of Medicine, Medical College, Trivandrum

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Drugs therapeutics is a dynamic process. What is essential may be obsolete tomorrow and a number of drugs are being introduced every day replacing old ones. The process of renewal and revision of indications of uses and misuses requires constant and periodic evaluation by competent authorities. The decision on this matter has to be communicated promptly to the agency that uses the drugs i.e., the doctors.

One has to take stock of the indications for the use of particular drugs; in other words one requires a dependable idea about the morbidity pattern and mortality prevalence. In other words we should know the number of diseases and the type of illness in the community and project the needs of necessary drugs for the present and future. The WHO has already classified the illness as per the International Classification of Disease Code and it should be made imperative for the medical practitioners to know them and use them in regular notification of morbidity. Then only can one have a strong data base on which requirements can be projected. So a change in the attitude of medical profession is required at the fundamental level. This informatics should be a part of the curricula of the medical student so that there is accountability of what one means when a diagnosis is made. The multiple systems of medical care in the same population is a great hinderance towards this goal. This has been overcome in countries where there is a socialised system of medical care. So the doctor and the authority knows what a particular entity means. Therefore one has to realise that ultimately planning for this need is basically a political issue. A large percentage of people still depend on native or Ayurvedic system of medicine and may use different systems at the same time. Therefore "Essential Drugs" come only under the purview of Modern Medical practice. There is an urgent need for the public for developing the correct type of medical system needed for them. One may have to take lessons from other developed countries. So we should know what drugs are needed for us and in what quantity for a period of time. Then we have to decide who should produce it and who should market it and distribute it. These are policy matters that require decision without which one cannot have clear goals. This will need curbing production of certain drugs immediately and promoting production of certain other drugs. This will mean buying or transferring of specific technology or knowhow from appropriate agency. A close look at the drug industry

now in our country will make one realise that a vast majority of drugs produced are non-essential based only on "economic self-interest"

At the practitioner level and at the institutional level close monitoring is required on drug use and abuse or misuse, i.e. there has to be a drug policy for the institution and for the state. The policy and implementation require monitoring by an appropriate technical group and this will need periodic revision depending on advances made in that particular area. A therapeutic code will have to be drawn up for the particular institution so that uniformity of management principles are possible for individual patient. A parallel improvement in diagnostic systems and methods is a must if this goal has to be achieved since without a correct diagnosis treatment is very often maltreatment or wrong treatment. The medical student and the doctor has to be oriented towards this situation. The public have to be educated that correct diagnosis way is time consuming and still in many cases correct "provisional" diagnosis is the only answer to "poly pharmacy" which is producing drug reactions and interactions

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# **Towards a People's Drug Policy: Role of People's Science Movement**

**Dr. A.R.Patwardhan**

Let us begin with a definition of People's Drug Policy. By People's Drug Policy, we mean—

- 1 A Drug Policy which is designed by the people, for the people for a definite goal Health for All
- 2 The cost of the drug should be such that everybody should be able to purchase a drug when it is needed for him.
- 3 The composition of the drug should be such that it should have a scientific reasoning for its formulation.
- 4 Utility and the safety of the drug should be established before it is marketed. If not found harmful, after marketing it, it should be withdrawn from the market
- 5 The drug should be marked by generic name.

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Dr. A.R. Patwardhan

Dr. Arunva Dakshata Mandal, Pune.

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6. The drug should be an 'essential' drug.
7. Harmful and toxic drugs must be eliminated
8. There should be a rigid Quality Control.
9. The drug should be available to a consumer at any given time.
10. There should be adequate information of the drug in the packing.
11. Research.

The present situation: At present the drug policy is governed by the multi-national firms and the Indian firms without any consideration of the welfare of the people. It seems that Government is quiet and inactive on this issue.

What do we mean by a drug? Drug itself is not our aim and object. Drug is a tool which helps in giving relief to a patient. It can prevent a disease, etc.... Under the pretext of modern technology and development, so many things like drugs, diagnostic aids, pesticides, high breed seeds and high breed animals have come in to our country or, pushed into our country by multi-national firms with the sole aim of earning profits. This has created an alarming situation in our country and in the Third World. All this is obstructing the formulation of our own policy. We can only fight this out with the help of People's Science Movement.

Around 1947, the annual sales of the drugs were around 15 crores of rupees. A decade before Hathi Committee (around 1963) the sales were around Rs 200 crores, and the sales after a decade of Hathi Committee are around Rs 1500 crores. And still we are catering to only 20% of the population. This position warns us to rectify the situation urgently. At present 70% of the drugs which are sold in the market are either useless, unnecessary or toxic. This error, if we continue to commit, will create an unprecedented harm to the Third World.

What we, the Arogya Dakshata Mandal, have done in the last 15 years? Around 1970, I wrote an article in a regional language (Marathi) in a popular magazine of Maharashtra (Kurloskar). The article was read by Pharmaceutical Industry people also. They had an informal discussion on the article and they felt that since this was a single handed effort, there is no need to take any cognisance of it. After knowing this, a group of like-minded people came together and we decided to fight this issue on a collective, community basis. Then we started taking group meetings and we also started telling the

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people that pharmaceutical companies are cheating us. They are selling harmful and hazardous drugs in our country though they are banned in their own countries. It was all new to the people. There was and there is always a question in the minds of the people that we do not know anything about a drug. Whatever is prescribed by a doctor is accepted by us. So we decided to meet the doctors and tell them the truth. For the last ten years, we got a very small response or no response to be more correct. Then we thought of taking the question in a wider perspective. In one of the meeting we had an experience worth remembering for all of us. It is like this - In a meeting of the people we were discussing about the baby foods, the bottle and the mischief of multi-national firms. With a lot of discussion and some scientific information, people appeared to be convinced, and the next question that followed was 'what is the alternative? On the same day, there was a meeting with the medical profession, and they also asked about the alternative to the baby foods. I just told them that the alternative to baby foods is---what your mother gave you when you were a child.

All these things made us to think very seriously for the last five years. Then we thought in the following way. To end the menace of dangerous drugs, we should impart health education to the people. This alone will succeed. This alone will create an impact both on the Government and the pharmaceutical firms.

### **Health Education**

What is Health Education? Health depends upon environment, food, clothing and shelter and the resources to buy the essential things. All these factors should reach the millions of our people. How can this be done? With the problem of illiteracy in our country, along with poverty, this becomes an extremely difficult proposition. What can be done in this situation? We started thinking on that. And the solution we have adapted today is non-formal education.

Health Science is nothing but a part of physical sciences. This was rightly thought by our Indian scientist, 'Sushrut' a thousand years back. He said that health sciences will improve with the help of physical science. You will get the reflection of the progress of physical science in health sciences. Once we have understood this concept of promoting physical or basic sciences for the masses, the question is that what exactly should be given to the people?

Then we derived some science experiments, programmes, for

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the people which will include the basic sciences and it will be correlated with the health sciences. To name a few of them (1) The metabolism in the body; (2) the absorption of water by the roots, compared with intestinal absorption; (3) experiments on sanitation, foods, environment, diseases, etc.

All these things we derived in such a way that the package can be given to illiterate men and women, school children and children not going to school. In short the package is for everybody. Let us take one concrete example.

We talk about ORT. To understand ORT people must know the basic science involved in it, —the bacteria—the limitations of the drugs, etc. Then the people are in a position to keep away from the drugs. Then only can they learn that drugs are not necessary in diarrheal diseases. This can only be achieved by People's Science Movement.

With the People's Science Movement, the Health Science Movement will automatically follow. This will lead us towards a People's Drug Policy.

The components of the Basic Science Movement—or the Health Science Movement—are as follows.

Part I. Our body and ourselves. This describes the anatomy and physiology.

Part II. The human being in the environment.

Part III. Information of the diseases and their remedy.

Once we have equipped our people with this basic science knowledge, they will be in a position for a 'Great Leap Forward'. The People's Science Movement starts from here onwards. The People's Science Movement will then be followed by a People's Drug Movement.

When the people know about diarrheal diseases, they will not take any drug for diarrhoea, which will result in downward trend in the sale of drugs. This is an example of indirect control by the People's Science Movement. The direct control would be when the people know about the side effects of Isonitil etc. and they will oppose the pharmaceutical companies, the doctors, the chemist and the government. The people can then organise such meetings themselves and resist the use of such drugs.

These are the examples of a consumer who is properly informed by the People's Science Movement. Such consumers alone can fight

against the harmful toxic and useless drugs. The informed consumer is a major force who control the People's Drug Policy

The informed consumer can then demand to amend the rules of Drugs and Magic Remedies Advertisement Act. Before the Hathi Committee there was only newspapers, magazines and radio - and thanks to the illiteracy in the country, the harmful and toxic drugs were not reaching the people. But with the TV media this has totally changed. The sale of so called nutritional products has increased tremendously. I will cite an example of our experience in this regard. We took about 100 workshops of consumer groups in Bombay from 1980 to 1983. We gave them the scientific information about breast feeding, and weaning foods. We used our own material for this. The result was that Glaxo had to recognise this in the Presidential Address of the Annual General meeting of the company. The Chairman said that Glaxo could not achieve the target of the growth rate of sales this year because of consumer campaign against the Baby Foods.

### **Of Pesticides and Veterinary Drugs**

After the Hathi Committee during the last few years the use of pesticides, chemicals and *veterinary* drugs had increased creating an alarming situation. The Hathi Committee never thought of these things in the People's Drug Policy. We feel that *Pesticides* and *Veterinary* drugs should be included in the People's Drug Policy.

Just like an ignorant patient taking tablet of Oxypren Butazone without knowing its toxicity and the limited benefits the tablet can give to the patient, the pesticides and the veterinary products are used in a similar way. This point forces us to include Environmental Education in the Science Movement.

F.D.A. America banned the use of antibiotics in the animal feeds about 20 years back, but it is still used in our country. This is causing a problem of resistance by the bacteria.

### **The Need for Re-writing the Science Text-books**

The present text-books of science are adversely affecting the People's Science Movement and the People's Drug Policy. The present text-books describe that the so-called Green Revolution is due to the big dams, canals, fertilizers, pesticides and tractors etc. And all this is called Modern Technology by the rich countries. Is it the truth? The text-books do not highlight the disasters of pesticides, etc. The school boy learns the first part only. When he goes to a

Medical College, he learns that the treatment of diarrhoea is nothing but killing the bacteria. And then he practices only antibiotics. If the vicious circle must be broken and for this we have to prepare our own science material.

I have highlighted in brief the correlationship between the People's Drug Policy and the People's Science Movement. We the members of Dakshata Mandal believe in this philosophy.

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# **Generic and Brand Name Controversy: A Sampl Survey**

**P.H. Rao**

## **Introduction**

Based on the Hathi Committee recommendations, the Drug Policy announced in 1978 banned marketing of five drugs, viz., Analgin, Aspirin, Chlorpromazine, Ferrous Sulphate, Piperazine and its salts under brand names. This ban was to be extended later to more number of drugs, based on the experience of this change. Arguments and evidence in favour and against the changes were forwarded by the interested parties. If the change is to be accepted successfully, the stand of doctors and the chemists, besides that of the manufacturers need to be examined. This paper is an attempt to assess the awareness of the doctors and chemists of the shift to generics. These two groups are important in taking the drugs to the people, the actual users.

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P. H. Rao, Fellowship Candidate, Indian Institute of Management, Bangalore

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### 3. Monthly sales wise

Less than Rs. 10,000	30
10,000 - 15,000	30
15,000 - 20,000	10
More than 20,000	30

## Findings of the Study

### A FROM THE DOCTORS SURVEY

1. *Awareness:* Only 75% of the doctors contacted were aware of the ban. However only 50% of them could list all the five drugs included in the ban.
2. *Prescribing habits:* 50% of the doctors were using only brand names and 42% were using both brand and generic names while 8% were using generic names with company's name. None was using generic name alone.
3. *Disposition towards the shift to generic names:* 61% of the doctors were in favour of the change, but qualified their opinion with statements like stricter quality control, limiting the ban to a group of drugs etc. 39% of the doctors who were against the change forwarded reasons like spurious drugs, selection of changes by chemists, etc. Some were of the opinion that brand names offer the advantage of allowing changing drugs without really changing the active substance, to give psychological satisfaction to the patients of better care.
4. *Perceived effects of the shift to generics:* This is presented in tabular form as below.

Effect	Response (%)			May be
	Yes	No	N.R.	
—Drugs will become cheaper	69	17	8	6
—Prescribing becomes tedious	50	47	0	3
—Better awareness of pharmacological activity	64	22	8	6
—Quality and bio-availability not assured	56	35	3	6
—Spurious drugs will flourish	72	22	6	0
—Patients do not accept generics	28	64	8	0
—Pharmacists find dispensing easier	72	22	6	0
—Substitution by chemists will increase	92	8	0	0
—Irrational combinations will be eliminated	80	11	6	3

## Objective of the Study

To assess the awareness of the ban on brand names among the doctors and chemists.

To examine the disposition of these two groups towards this change.

## Methodology of the Study

With the help of a pretested questionnaire, the desired information was collected from the doctors and the chemists. A sample of 50 doctors and 35 chemists, in Bangalore city, was the base for the present study.

## Sample Characteristics

### A. DISTRIBUTION OF DOCTORS

	(Percent)
1. <i>Setting wise</i>	
Private practices	42
Nursing homes	14
Government Hospitals	8
Private Hospitals	36
2. <i>Qualification wise</i>	
MBBS	39
BDS	5
MD, MS	23
Diploma, FRCS etc.	33
3. <i>Experience wise</i>	
Less than 2 years	12
2—5 years	31
6—10 years	25
More than 10 years	32

### B. DISTRIBUTION OF CHEMISTS

	(Percent)
1. <i>Qualification wise</i>	
D. Pharm	56
Degree & D. Pharm	31
B. Pharm	13
2. <i>Experience wise</i>	
Less than 2 years	31
2—5 years	38
6—10 years	13
More than 10 years	18

— Important drugs will not be available	50	31	11	8
— Helps rational therapy	64	22	8	6
— Agress with their price consciousness	72	8	17	3

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N.R.      —      No response

## B. FORM THE CHEMIST SURVEY

1. *Awareness*: 44% were aware of the ban and could list all the five drugs. 38% were aware of some of the five drugs. 18% were unaware of the ban.

2. *Dispensing Patterns*: Percent of Generic prescriptions

0	18%
1 to 20	56%
21 to 40	18%
More than 40	6%

Percent of sales without prescription

Nil	13%
1 to 10	50%
1 to 20	31%
More than 20	6%

3. *Preceived effects of the shift to generics*:

Effect	Response			May be
	Yes	No	NR	
— Margins will decrease	12	88	0	0
— Prices will decrease	69	31	0	0
— Medical reps will come less often	44	44	12	0
— Ordering drugs will become difficult	50	44	6	0
— Dispensing will be easier	50	44	6	0
— Doctors will find the change difficult	72	25	0	0
— Inferior quality drugs will flood the market	88	6	0	6
— Patients will find the change confusing	69	25	0	6
— Substitutions by them will be encouraged	69	31	0	0

N.R. = No response

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# **Towards a People's Drug Policy: Consumer Education**

**P.H. Rao**

## **Introduction**

Rational drug therapy is an essential component of providing primary health care. Production and marketing of the necessary drugs is the first step in rational drug therapy. Prescription of rational drugs is the next step. As the actual user of the drugs the consumer, in the present system, has little role in the process of drug therapy. This is basically because of consumer unawareness and ignorance. As the ultimate beneficiary (or sufferer) of the drug therapy, consumer should be aware of the various aspects of drug utilization. An educated consumer may prove instrumental in making the present drug therapy more rational. This, however, requires conscious efforts to provide relevant information to the consumers.

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P.H. Rao, Fellowship candidate, Indian Institute of Management, Bangalore

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**Content of Information for Consumer**

1. What is drug? How it works? Its role in medical and health care.
2. Most common diseases. Their etiology. The concept of essential drugs.
3. The present day status of drug availability in the country. Matching between the drugs needed and that available. Reasons for the present condition.
  - Manufacturer's priorities in production of drugs
  - Marketing practices
    - generic vs brands
    - sales promotion techniques, etc.
4. Hazardous, bannable (irrational combinations) and banned drugs—Reasons for their ban and a list of these drugs.
5. Role of the prescriber. Economics of therapy. Behaviour of the prescriber.
  - Pressure of manufacturers
  - Pressure of peers
  - Pressure of consumers
6. Role of self-medication
  - where and when self-education is safe, appropriate and desired
  - where and when self-medication is harmful and to be avoided
7. Need for compliance with prescription
  - concept of adequate dosage levels
  - under dosage
  - shelf-life or expiry period
8. Knowledge of probable side effects, precautions to be taken, conditions where drugs need to be avoided (children, pregnancy, chronic disorders, etc.)
9. When confronted with any out of the way situations, what is expected of the consumer—Reporting to relevant persons.
10. Consumer role in propagating (sharing) their experience and knowledge with others.

**Media for Information Dissipation**

Identify and segment the target population, based on their characteristics.

Selection of the media

Mass Vs. Personal

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—Advantages and disadvantages of these media.

**Who should do it?**

- Role of manufacturers and prescribers in Consumer Education.
- Role of consumer activist groups and voluntary agencies
- Preparation of the education materials
- Desired qualities of the message.

**Some Questions Consumer Should Ask**

- Are there any cheaper drugs available?
  - generic/different brand/different group with same pharmacological activity.
  - Are the dosage and number of formulations prescribed necessary/adequate?
  - What are the probable side effects? Precautions to be taken.
  - Is the expiry date over.
  - Are the drugs prescribed safer with children, pregnant women, specific chronic conditions, etc.
  - Are these drugs safe for self-medication?
  - What are the consequences of non-compliance? When to discontinue, if the need arises?
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# **Fighting for a People's Drug Policy— KSSP Experience**

**Dr. B. Ekbal**

The Kerala Sastra Sahitya Parishad, the People's Science Movement in Kerala intervenes in areas like Health, Education, Ecology and Problems of War and Peace. In the field of health, KSSP is very strongly questioning the relevance of the present day health delivery system which is curative oriented, individualised, institutionalised and highly costly and catering to the needs of only a wealthy minority. KSSP feels that a People's Health Movement alone can change the health delivery system in favour of the rural poor. KSSP has been striving for the last few years by various means to initiate such a movement in our country. With this purpose KSSP is at present organising health camps, health education classes, people's theatre forms and audiovisual campaigns and field studies on an extensive scale..

Although granting that drugs and hospitals have only minimal role to play in achieving a healthy living for the poor, we felt that exposing and fighting the anti-people and exploitative tactics of the drug companies should play a major role in the campaign for a people's Health Policy for our country. The aim is two fold; on the one hand we should demystify pharmaceutical products as far the people at large are concerned and on the other hand this can be used as an entry point into the medical profession so as to conscientise the doctors and medical students on the wider health issues.

KSSP started its campaign for a People's Drug Policy from the World Health Day, April 7th, 1984. With 1½ years intense campaign we could make the drug issue a subject of public debate, make people aware of the unethical marketing practices of drug companies and also could identify and organise a number of doctors and medical students who are socially conscious and are ready to wage a fight for a people's Drug Policy.

We started the campaign with a few major demands. These are demands for the production and distribution of essential drugs, banning of non-essential irrational and dangerous drugs, better quality control of drugs and implementation of the Hathi Committee Recommendations like nationalisation of the drug industry, strengthening of the public sector, introduction of generic names and updating of the national formulary. Throughout the campaign these demands are explained in detail to the people with the help of documented facts, figures and authentic governmental and non governmental resource materials. The campaign started by conducting seminars simultaneously in all the 14 districts of Kerala on the World Health Day. The theme paper was presented by a KSSP activist doctor. Representatives of doctors' organisation, Medical Representatives and Pharmacist organisations and eminent personalities took part in the discussion. Later 45 Zonal conferences were organised taking the campaign still further forward. By the end of the year most of the 600 units of KSSP evenly distributed throughout Kerala organised seminars attended by hundreds of doctors and thousands of people.

Apart from lectures and seminars a number of articles on the various aspects of the drug issue were published both in KSSP journals and in other popular magazines. Two books were published and the study done by Medico Friends Circle on Analgesics and Antidiarrhoeals were reprinted and popularised among doctors. We are at present summarising the Hathi Committee Report which will be published later. Through the Rural Science Forums of KSSP, about 2000 wall news papers explaining the various aspects of the drug issue were displayed in the rural areas. Thus the message was communicated to the rural people.

The Science Cultural Programme organised by KSSP is a powerful medium for the popularisation of ideas on various issues. Every year Science Cultural March will be organised from one end of

Kerala to the other end taking the message of science to the people in a big way. A few items on the health issue including drug were included in the last two jathas which attracted the attention of the people.

KSSP units are at present functioning in the Medical Colleges also. With the help of these units seminars and discussions are regularly conducted in the medical colleges. A number of articles have already appeared on the drug issue in the medical college magazines. Recently the Trivandrum Medical College Students opened Dr. Olle Hansson corner to sell books on drug issue in the All India Paediatrics Conference conducted in the Medical College campus. KSSP activist doctors who are also members of professional bodies like Indian Medical Association and Kerala Government Medical College Teachers Association and Kerala Government Medical Officers Association and Medical Students Organisation have made the drug issue a live subject of discussion in these bodies and could make these professional bodies take positive stand on this issue on many occasions.

We coupled our campaign on the Bhopal Genocide with the Drug campaign effectively. Bhopal as the inevitable outcome of the multinational exploitation of the MNCs including that in the pharmaceutical sector could be focussed during the Bhopal campaign.

We are at present organising an All India Seminar on Drug Industry A decade After Hathi Committee to mark the occasion of the 10th Anniversary of the publication of Hathi Committee recommendations. Since we have a public sector pharmaceutical company in Kerala (Kerala State Drugs and Pharmaceutical Industry) supplying about 45% drugs to the Kerala Health Service a call to strengthen KSDP is already made so as to make it capable of producing all the essential drugs to the Health Services. With this end in view a seminar on 'A Drug Policy for Kerala' will be organised later.

What are the concrete results of KSSP campaigns so far?

1. The drug issue has been already developed into a subject of public debate.
  2. People from all walks of life are now aware of the various issues involved, like essential versus irrational and dangerous drugs, exploitative tactics of the MNCs and the indifference on the part
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of the Government in implementing the Hathi Committee recommendations.

3. A number of doctors and medical students sympathetic with our views are identified and organised.
  4. The prescription habits of doctors are slowly but definitely changing.
  5. The sale of irrational and dangerous drugs is coming down.
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## **Resolutions passed in the Seminar**

### **1. Resolution on Patents Act**

It was only after appropriate changes in the Patents Act in 1970 that a significant technological boost could be observed in the country's drug industry. Of course, several other factors, namely the contributions of the public sector, national labs and the R&D activities of Indian Private Sector have also played a significant role towards this development. Nonetheless the introduction of most of the 70 odd drugs in India since 1972 could not have been possible if we had continued with our old Patents Act or joined the Paris Convention since the international patents for many of these are due only in late 80s or 90s.

Undermining the technological capabilities that have been built over the years, there is a move in certain quarters to join Paris Convention. While it is not likely to accrue any significant benefits to the drug industry or improve its technological strengths, significant changes will have to be effected in our present Patents Act. These changes will be particularly detrimental to the growth of Indian sector, public, private or small-scale-alike.

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Releasing the importance of continuing the present progressive Patents Act for the growth and technological development of the country's drugs industry, this house resolves that India should under no circumstances join the Paris Convention at this critical juncture when the indigenous drug industry is poised for a great leap forward.

## **2. Resolution on the consolidated list of hazardous products**

People all over the world are becoming increasingly concerned with the unrestrained world trade in a number of hazardous products like drugs, pesticides, chemicals etc. that are recognised as hazardous and even banned in many countries.

As estimated 575,000 people die every year due to pesticide misuse and many more are crippled by it. Yet several toxic chemicals and drugs like chloroform and cliquinol, banned in many developed countries are exported to the Third World and consumed by an unsuspecting populace. Many other dangerous products like the infamous Dalkon shield, a intrauterine device banned in most countries are dumped on the Third World.

As a first step in the direction of resolving some of the life threatening problems caused by the largely unregulated trade in banned and restricted products a new directory has been published by the United Nations known as "The consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by Government." This list based on a 1982 UN General Assembly resolutions calling for preparation of such a directory, contains critical information on a regulatory decisions, restrictions and bans taken by National Governments on harmful pesticides, dangerous pharmaceuticals, hazardous consumer products and toxic industrial chemicals. This directory is invaluable for Governmental and non Governmental organisations to fight the dangers posed by the dumping of these products in the Third World.

The first UN directory triggered off stiff opposition from some industrialised countries and the corporate sector. Twice the U.S. has voted against support for the directory project in the UN General Assembly and at the same time U.S. Congress has cynically permitted the export of products banned in their home market. Now the U.S. and a number of other industrialised countries and the corporate sector are trying to modify the second edition of this "consolidated list" directory, removing trade names and otherwise diluting it.

We, who have participated in this seminar resolve to demand the continuation of this directory in its original form and oppose attempts to dilute it and demand the various ministries of our Government to use this directory and contribute to it positively..

### **3. Resolution on injectable and implant contraceptives.**

Recently there is a move from the Family Planning Organisation drug companies and the Government to introduce injectable contraceptives and the other long-term hormonal preparations in the form of implants at a mass-scale in the EP programme. The ICMR has been carrying out multicentric studies on these for the last few years.

One of the injectable contraceptives, Depoprovera is not cleared by the FDA in USA. However, it is being actively pushed in the Third World countries as a birth control drug. While the ICMR has discontinued testing of Depoprovera, another drug, NET-EN, which is equally dubious in character is being tested by it and all results suggest that it is being done very inadequately and with scanty follow-up to find out its cancerous and other long-term effects.

Therefore, this seminar strongly opposes introduction and continued testing of injectables & implant contraceptives.

### **4. Resolution on Indian Drug Industry**

This conference reiterates the demands of K.S.S.P.

1. To increase the production of essential drugs to meet the basic need of the ailing population of our country.
2. Ban the import and production of non essential drugs our country.
3. Impose strict quality control on the drugs produced by pharmaceutical houses.
4. Implement Hathi Committee recommendations.
5. Formulate a people oriented drug policy.
6. Requests all concerned individuals and groups to organise health and people's science movements, at the grass-roots level, commensurating with the other democratic movements to ensure social justics.

### **5. Resolution on Breast Feeding and infant feeds**

While the breast feeding campaign has had an important impact in revealing the harmful effects of the propagation of packaged infant foods, it is essential that the concerns of women be made more central to the campaign. Specifically, the requirements of working

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women should be taken into more serious account than has hitherto been the case. We resolve therefore that the Peoples Science Movements take up action towards providing

1. More scientific information on the time length for adequate breast feeding.
  2. The production of cheaper infant foods which combine convenience with low cost.
  3. Attitudes towards child and infant care that recognise the responsibilities of both parents.
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## **Medical Students to fight for a People's Drug Policy**

The Medical students from different Medical Colleges in Kerala attended the seminar on Indian Drug Industry "A decade after Hathi Committee" organised by Kerala Sasthra Sahithya Parishad in large number and declared the following decisions in the seminar.

1. Action groups comprising of medical students, Post gradutaes and doctors will be formed in all the Medical Colleges to study the drug issue in details, publish literatures and organise seminars and conduct surveys on various aspects of drug usage and misuse.

2. Medical students shall campaign for introduction of

(a) Hospital formulary

(b) Drug economics in the Medical curriculum and

(c) Generic names instead of brand names of drugs in all the Hospital Records.

3. Medical students shall request professional bodies not to accept funding from pharmaceutical industry to organise medical conferences.

4. Medical students shall request the hospital authorities that drug companies should not be permitted to organise meetings of the house surgeons and doctors to popularise their products.

5. Dr. Olle Hanson who fought the unethical marketing practices of the Swedish multinational giant Ciba-Geigy and forced them to withdraw their hazardous drugs Mexaform and Tanderil from world market expired on May 24th this year. Dr. Olle Hansson Day will be observed on the death anniversary of Dr. Hansson every year to focus attention of the medical profession on the various aspects of the drug issue.

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# Medical Students to Fight for People's Drug Policy

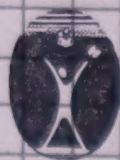
The medical profession has a long history of serving the people, but in recent years it has become increasingly aligned with the interests of the pharmaceutical industry. Medical students, who are the future of the profession, must take a stand against this trend and fight for a people's drug policy.

One of the main problems with the current drug policy is the high cost of prescription drugs. This is due to a combination of factors, including the high cost of research and development, the power of pharmaceutical companies, and the lack of competition. Medical students must understand the impact of these costs on patients and work to ensure that drugs are affordable for all.

Another issue is the overuse of prescription drugs. Many patients are prescribed drugs that they do not need, leading to unnecessary side effects and increased costs. Medical students must be educated on the proper use of drugs and encouraged to question unnecessary prescriptions.

Finally, medical students must fight for a drug policy that prioritizes the needs of the people over the profits of pharmaceutical companies. This includes supporting policies that increase transparency, promote competition, and ensure that drugs are accessible to all.





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